Montgomery County Community College

Request for Proposals

#02-080315RFP-01

Date Issued: July 14, 2015

Virtual eLearning Platform in Downstream Processing

DUE DATE/TIME: August 3, 2015, 2:00 P.M. EST

Time and Date of Pre-Proposal Conference: July 20, 2015 at 10:00 A.M. EST
Deadline for Inquiries: July 22, 2015 by 10:00 A.M. EST
Deadline for Sealed Proposals: August 3, 2015 by 2:00 P.M. EST
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INVITATION TO SUBMIT PROPOSAL

The Board of Trustees for the Montgomery County Community College will receive proposals for the following: **Virtual eLearning Platform in Downstream Processing**

Bid Documents, including the Specifications, may be obtained at www.mc3.edu/purchasing.

There will be a voluntary pre-proposal meeting on July 20, 2015 at 10:00 a.m. Interested Proposers will meet at Montgomery County Community College, 240 DeKalb Pike, College Hall, Room 146, Blue Bell, PA 19422 at 10:00 A.M. To attend this meeting, please RSVP by emailing purchasing@mc3.edu no later than July 18th.

Proposal Documents, including specifications, will be available to interested Proposers beginning July 15, 2015.

Inquiries for information regarding this Request for Proposals should be submitted in writing and directed to:

Director of Procurement
Montgomery County Community College
Fax: (215) 641-6516
Email: purchasing@mc3.edu

Sealed Proposals shall be submitted by mail, hand-delivery or express courier to: Montgomery County Community College, Purchasing Department, Room 121 College Hall, 340 DeKalb Pike, Blue Bell, PA 19422 by 2:00 P.M. on August 3, 2015.

Proposals must be submitted on forms included in the bidding documents and must be accompanied by Proposal Security and Non-Collusion Affidavit in accordance with the Instructions to Bidders. Proposals shall conform to all other requirements as more fully set forth in the bidding documents, including compliance with all applicable laws and regulations. All proposals submitted are valid for acceptance by the College and may not be withdrawn for one hundred twenty (120) days after proposal opening. The College reserves the right to reject any or all proposals or any part thereof or items therein and to waive informalities and/or technicalities as it deems best to protect its interest.

END OF DOCUMENT
INSTRUCTIONS TO PROPOSERS

1. PROPOSAL DOCUMENT AVAILABILITY; PRE-PROPOSAL MEETING

A. The Proposal Documents have been prepared by the Purchasing Department of the Montgomery County Community College located at 340 DeKalb Pike, Blue Bell, PA 19422. The Proposal Documents are made available only for the purpose of obtaining Proposals for this Project. Their availability does not grant a license for other purposes.

B. Upon receipt of Proposal Documents, Proposer shall verify that the documents are complete, and shall notify the Purchasing Department should the documents be incomplete, or upon finding discrepancies or omissions in the Proposal Documents. Proposer shall be responsible for the completeness of their set of Proposal Documents. No allowance or concession will be made to a Proposer who complains of missing portions of Proposal Documents subsequent to the award of Proposal. All requests for clarifications must be in writing and received by the College no less than seven (7) days before the Proposal due date. All clarifications, modifications and corrections to the Proposal Documents shall be issued in the form of Addenda and shall be forwarded to all known Proposers. Addenda listing revisions and changes to the Proposal Documents shall become a part of and take precedence over original Proposal Documents and shall be so honored by Proposers in preparing their Proposals.

C. Pre-proposal Meeting. A voluntary pre-proposal meeting will be held on July 20, 2015 at 10:00 a.m. to make certain that the specifications are clearly understood. Interested Proposers will meet at Montgomery County Community College, 240 DeKalb Pike, College Hall, Room 146, Blue Bell, PA 19422 at 10:00 A.M. Parties interested in attending this meeting should RSVP by emailing purchasing@mc3.edu no later than July 18, 2015.

D. The quantities of Products in the Specifications and/or Proposal Form are merely estimates of the College’s needs, and are provided solely for proposal purposes so that the Proposer can provide a price; the College is not committing to purchase such estimated quantities of Products. The College reserves the right to purchase more, less or none of the Products as the College determines it requires in the College’s sole and absolute discretion. The Products will be requisitioned by the College on an as-needed basis. The Contractor shall provide the College with Products within the time limits specified in the Contract for the price proposed for such Product.

2. DEFINITIONS

A. Addenda: Written and/or graphic instruments issued by the College prior to the Proposal deadline which modify or interpret the Proposal Documents by additions, deletions, clarifications or corrections.

B. College: Montgomery County Community College, its agents, employees and/or authorized representative.
C. **College Property:** Shall mean any real property owned or operated by the College, and all buildings and improvements thereon, and any personal property, systems and equipment located therein or thereon.

D. **Contract Documents:** Proposal Documents, Proposer’s completed Form of Proposal (but only with those exceptions accepted by the College as noted in the Agreement (hereinafter defined), and the completed Form of Agreement between College and Contractor (hereinafter “Agreement”), and any other documents required to be completed per the Proposal Documents.

E. **Contractor:** Successful Proposer, i.e., Proposer to whom contract is awarded.

F. **Products:** The **Virtual eLearning Platform in Downstream Processing**, including, without limitation, all software, licenses, goods, products, equipment, and materials (including, without limitation, all necessary labor and manufacturing necessary to supply such items to the College in the form or manner required for the College to take beneficial use of such items and as may be further detailed in the Specifications) identified to be supplied under the Contract as detailed in the Specifications.

G. **Proposal Deadline:** The date and time which the College will receive and open sealed Proposals as identified in the Invitation to Submit Proposal.

H. **Proposal Documents:** Invitation to Submit Proposal, Instructions to Proposer, Proposal Form, form of Non-Collusion Affidavit, form of Agreement, Specifications, Campus Map and other sample proposal and contract forms, and all Addenda issued prior to Proposal opening.

I. **Proposal Sum:** Monetary sum identified by Proposer in Proposal form.

J. **Proposer:** Person or entity submitting a Proposal.

K. **Services:** All services (including, without limitation, all supplies and equipment necessary to perform such services) identified to be provided under the Contract as detailed in the Specifications, such as, without limitation, installation of software, trouble shooting, training, and maintenance.

L. **Specifications:** The drawings, plans and specifications included with the Proposal Documents that provide the technical details of the Products and Services.

### 3. **TERM OF CONTRACT**

It is the intent of the College to award a contract to a single Contractor for Products and Services. The contract shall commence no later than thirty (30) days after notice of award. If the College is not satisfied with the performance of the Contractor, then the Contract may be terminated at such earlier time as provided for in the Agreement.
4. **PREPARATION AND SUBMISSION OF PROPOSALS**

A. Proposer shall be solely responsible for the delivery of their Proposal in the manner and time prescribed. All Proposals must be received by the College at the place designated in the Invitation to Proposal, prior to the time designated in the Invitation to Submit Proposals for Proposal opening. Proposals received after the time advertised for Proposal opening shall be returned to Proposer unopened.

B. Proposals shall be prepared and submitted on forms furnished by the College. All blank spaces shall be filled in, by typewriter or ink, and amounts shown in both words and numbers. In case of discrepancy, the written words shall be considered as being the Proposal Sum. Proposals should be prepared simply, providing straightforward and concise responses to requests for information and descriptions of qualifications and capabilities. Proposals having any erasures or corrections must be initialed by the Proposer in ink.

C. Proposals will remain firm and non-withdrawable for one hundred twenty (120) days after the opening of Proposals, and will thereafter remain firm and non-withdrawable until the Proposer provides written notice to the College’s Purchasing Department that the Proposal has been withdrawn.

D. The Proposal Form shall be signed in accordance with the following:

   (1) If the Proposer is an individual, the Proposal shall be executed by him, personally; his signature shall be witnessed; his business address shall be stated, and any trade name employed in the conduct of his business shall be stated.

   (2) If the Proposer is a partnership, the Proposal Form shall be executed in the name of the partnership by each of the partners, or a general partner authorized for this purpose; the signatures of the partners shall be witnessed; the business of the partnership shall be stated; and the business address of the partnership shall be stated.

   (3) If the Proposer is a corporation, the Proposal Form shall be executed in its name and on its behalf: (a) by the President or Vice President and attested by the Secretary or Assistant Secretary, and the Corporate Seal shall be affixed; or (b) by a duly authorized agent of the corporation whose authority to act, as of the date of the Proposal, shall be established by a certified copy of a resolution by the Board of Directors of the proposing corporation authorizing said agent to sign the Proposal on behalf of the corporation, submitted with the Proposal. The business address of the corporation and state of incorporation shall be stated.

   (4) If the Proposer is a limited liability company, the Proposal Form shall be executed in its name and on its behalf: (a) by all of the members if the company is member-managed, or by the managing member if the company is manager-managed, or (b) by a duly authorized agent of the company whose authority to act, as of the date of the Proposal, shall be established by a certified copy of a resolution by the members of the proposing company authorizing said agent to sign the Proposal on behalf of the company, submitted with the Proposal. The business address of the company and state of formation shall be stated.
(5) If the Proposer is a joint venture, each party of the joint venture shall execute the Proposal Form under their respective seals in a manner appropriate to such party as described above.

E. All Proposals, including required enclosures if applicable, shall be submitted in a sealed opaque envelope, clearly identified with Proposer’s name and the name of the Services subject to the Proposal. The envelope should also contain a notation that it should not be opened until the time specified for Proposal opening. Proposal envelopes not bearing this notation and opened in error will not receive consideration. If a Proposer elects to submit a Proposal by mailing rather than hand delivery, the sealed Proposal envelope described above shall be enclosed in a mailing envelope and addressed to the College, and must be received prior to the date and time specified for Proposal opening. Formal sealed proposals may be submitted by mail, hand-delivery or express courier to:

Montgomery County Community College
Purchasing Department
Room 121 College Hall
340 DeKalb Pike
Blue Bell, PA 19422

F. Addenda. Prior to the opening of Proposals, Proposer may be furnished bulletins for additions, corrections, or modifications to Contract Documents. These bulletins, in the form of addenda, are to be included in the Proposal and are part of the Contract. Failure of the Proposer to acknowledge any/all Addenda on his Proposal may be sufficient cause for rejection of his Proposal. The College intends that all Proposers shall have equal access to information relative to this RFP, and that this RFP contains adequate information. No information communicated, either verbally or in writing, to or from a Proposer shall be effective unless confirmed by an addendum to this RFP, or in the Proposal. It is the responsibility of each submitting Proposer to ascertain prior to submitting its response that all issued Addenda have been received. Addenda will be posted on the College’s purchasing web site at http://www.mc3.edu/purchasing.

G. References. It is the College’s position that only a Contractor who has demonstrated the ability to successfully deliver Products and Services to an educational facility similar in size and configuration to the College can deliver products and services at the level required by these specifications. Therefore, these specifications have as a standard that all references have a minimum rating of “acceptable performance.”

Each Proposer shall submit as part of its Proposal:

- All current service contracts in PA, to a maximum of ten (10). Educational facility contracts preferred.

- All references to be complete with name, contact individual, location, phone number, and type of facility.
H. **Financial Statements.** Proposer shall submit a copy of its financial statements upon request by the College.

I. **Finality of Decision.** Any decision made by the College, including the Contractor selection, shall be final.

J. **Release of Claims.** Each Proposer by submitting its Proposal releases the College from any and all claims arising out of, and related to, this RFP process and selection of a Contractor.

K. **Contractor Bears Proposal Costs.** A recipient of this RFP is responsible for any and all costs incurred by it or others acting on its behalf in preparing or submitting a Proposal, or otherwise responding to this RFP, or any negotiations incidental to its Proposal or this RFP. All Proposals submitted will become the property of the College.

L. **Disclosure of Proposal Content.** The laws of the Commonwealth of Pennsylvania require public information be available for examination by all interested parties. No Proposals shall be disclosed until after an award has been made. The College reserves the right to destroy all Proposals if the RFP is withdrawn; the award of the Contract is withdrawn; or otherwise in the normal course of business. Trade secrets or proprietary information submitted by a Proposer in connection with this procurement transaction shall not be subject to public disclosure (except as required by law); however, the Proposer must invoke protection prior to or upon submission of the data or the materials, and must identify the data or other materials to be protected and state the reason why protection is necessary. **Proposers shall submit, in a separate section of the Proposal, any information considered proprietary and any copyrighted material and clearly identify the information as proprietary and/or copyrighted information. Proposers may not declare their entire Proposal proprietary nor may they declare proposed pricing to be proprietary.** References may be made within the body of the Proposal to proprietary information; however all information contained within the body of the proposal not in the separate section labeled proprietary shall be considered public information.

M. **Exceptions to RFP.** Any exceptions to the terms and conditions contained in this RFP or any other special considerations or conditions requested or required by the Proposer MUST be specifically enumerated by the Proposer and be submitted as part of its Proposal, together with an explanation as to the reason such terms and conditions of this RFP cannot be met. The selected Contractor(s) shall be required and expected to meet the RFP requirements as set forth in this RFP in their entirety, except to the extent exceptions are expressly set forth in the Contractor’s Proposal and those exceptions are expressly accepted by the College and expressly incorporated into the Agreement in writing.

N. **Oral Interview.** The College may require qualified Proposers to participate in an oral interview and negotiation process to discuss their Proposal and to answer any questions the College may have regarding the RFP and Contractor’s Proposal.
O. **Inquiries.** Inquiries for information regarding this Request for Proposals should be submitted in writing and directed to:

  
  Director of Procurement  
  Montgomery County Community College  
  Fax: (215) 641-6516  
  Email: purchasing@mc3.edu  

P. **Number of Copies.** An original, so marked, and 1 copy, so marked, for a total of 2 of your Proposal are required. We also request that an electronic copy in PDF format be submitted on an accompanying compact disc or flash drive. Submit proposals in a sealed envelope marked as follows:

  [Name of Submitting Firm]  
  Proposal for Virtual eLearning Platform in Downstream Processing  
  RFP #02-080315RFP-01  
  Attention: Purchasing Department  
  Time/Date Due: 2:00 P.M. EST, August 3, 2015

Proposers are responsible for having their Proposal stamped by Purchasing Department staff before the deadline for receipt of proposals. The College will not assume responsibility for reproduction where an insufficient number of copies have been supplied. In any such case, College will notify the Proposer of the deficiency and request that the appropriate number of copies be delivered within 24 hours. Failure to comply with this or other requirements of this Request for Proposal shall be grounds for the College to reject such proposals. Telegraphic or facsimile submission of proposals is not acceptable and any such proposals will not be considered. Nothing herein is intended to exclude any responsible Proposer or in any way restrain or restrict competition. All responsible Proposers are encouraged to submit proposals.

5. **MODIFICATION AND WITHDRAWAL**

Proposals may not be modified after submittal. Proposals may be withdrawn after submittal, provided Proposer makes his request to withdraw in writing and the request is received prior to the time specified for Proposal opening. Negligence by Proposer in preparing his Proposal confers no right of withdrawal or modification of his Proposal after such Proposal has been opened.

6. **QUALIFICATIONS**

Prior to the award of contract, College may require satisfactory evidence to show that the Proposer is fully prepared in every way to perform the Contract timely and that he has been regularly engaged in such business. Proposer shall be prepared to furnish evidence that all certificates and public licenses have been properly maintained, are current, and shall attest that his company has never been defaulted on any public contract. The College may make such reasonable investigations as deemed proper and necessary to determine the ability of a Proposer to perform the work. The Proposer shall furnish the College all such information and data.
7. **COLLUSIVE PROPOSALS**

   A. More than one Proposal for one contract from an individual, partnership, corporation, company or an association under the same or different names will be grounds for rejection of all Proposals in which such Proposer is interested. Any and all Proposals will be rejected if there is any reason for believing that collusion exists among any of the Proposers. Participants in such collusion will not be considered in future Proposals.

   B. By submitting its Proposal, the Proposer certifies that it has not combined, conspired or agreed to intentionally rig, alter or otherwise manipulate, or to cause to be rigged, altered or otherwise manipulated its Proposal for the purpose of allocating purchases or sales to or among persons, raising or otherwise fixing the prices of the products or services, or excluding other persons from dealing with the College.

   C. By submitting its Proposal, the Proposer certifies that its proposal is made without collusion or fraud and that it has not offered or received any kickbacks or inducements from any other Proposer, supplier, manufacturer or related entity in connection with its proposal; and that it has not conferred on any public employee having official responsibility for this procurement transaction any payment, loan, subscription, advance, deposit of money, services or anything of more than nominal value, present or promised.

   D. Proposer shall submit with their Proposal, a Non-Collusion Affidavit in the form contained in the Proposal Documents.

8. **RESERVATION OF RIGHTS**

   The College reserves the right, in its sole and absolute discretion (for this provision and all other provisions contained in this RFP), to accept or reject, in whole or in part, any or all Proposals with or without cause. The College further reserves the right to waive any irregularity or informality in this RFP process or any Proposal, and the right to award the Contract to other than the Proposer submitting the best financial proposal (low bidder). The College reserves the right to request additional information from any or all Proposers. The College reserves the right to negotiate with one or more Proposers concerning their Proposals. The College reserves the right to award contracts to multiple Proposers.

9. **PROPOSAL REJECTION**

   The College reserves the right to reject any and all Proposals, or parts of a Proposal, when a rejection is in the College’s interest. The College reserves the right to reject a Proposer if he is not in a position to perform the contract or has previously failed to perform similar contracts properly or on time.

10. **CONTRACT**
A. The College reserves the right to award a contract for one or more of the items set forth in the Specifications, or for all items set forth in the Specifications.

B. The College will notify the selected Proposer of the College's intent to accept his Proposal and to make a formal award of contract to him by the Notice of Intent to Award. The College will include with the Notice of Intent to Award the Agreement to be signed by the successful Proposer. Within ten (10) days of receipt of the Notice of Intent to Award, the successful Proposer shall furnish (1) Certificates of Insurance as required pursuant to Section 13 of the Instructions to Proposer and the Specifications; and (2) the signed Agreement. The Insurance Certificates and Agreement shall be submitted to the College’s Purchasing Department within the required time period.

C. The entire integrated agreement between the College and Contractor in connection with the supply of Products and Services shall constitute the “Contract Documents” and form the Contract.

D. Failure of the Proposer to whom Notice of Intent to Award has been given to deliver appropriate Certificates of Insurance, or execute the Agreement within the time specified, shall constitute a default by such Proposer and the College may, at its sole discretion, award the contract to another Proposer or re-advertise for Proposals, and the defaulting Proposer shall pay to the College the difference between the amounts of his Proposal and any higher amount for which the College may contract for the required services, plus any advertising, consulting, legal or other expenses incurred by reason of the default. The College may, in its sole discretion, extend the time period for submission of the above items, upon request of Proposer.

11. STANDARD OF QUALITY

The various Products and Services specified in the Specifications by name or description are given to establish a standard of quality and of cost for Bid purposes. It is not the intent to limit the Bidder to any one Product or Service specified but rather to describe the minimum standard. When proprietary names are used, they shall be followed by the words “or substitution meeting or exceeding the minimum standard of quality, as determined by the College as evidenced by Addenda.” A Proposal containing a substitution which does not meet the Specifications may be declared non-responsive. Where Products or Services are listed with the words “No Substitutions”, these items are proprietary and the sole acceptable source for these Products and Services, and no substitutions will be permitted.

12. INSURANCE

Contractor shall carry such liability insurance as set forth below to fully protect the College from claims which may arise out of or result from the Contractor’s operations under the Contract and for which the Contractor may be legally liable, whether such operations be by the Contractor or by a subcontractor or by anyone directly or indirectly employed by any of them, or by anyone for whose acts any of them may be liable. No Services shall be started until the College has been provided Certificates of Insurance executed by an insurer licensed and qualified to do business in the Commonwealth of Pennsylvania on a standard form provided by the insurer.
stating their intention to provide insurance to the Contractor in accordance with these insurance requirements. All Certificates of Insurance must indicate that the College has (through endorsement to the policy) been specifically named as an additional insured. The Certificate of Insurance must also provide that the policy will not be changed, cancelled or allowed to expire until at least thirty (30) days prior written notice has been provided to the College. Such insurance limits shall remain in full force and effect during the term of the Contract. Said insurance certificate must be provided to the College prior to commencement of Services under the Contract. The certificates of such insurances shall carry an endorsement that the Insurance Company will defend the College as a party in the event the College becomes a party to litigation as a result of the activities or negligence of the Contractor, sub-contractor, or any direct or indirect employee of same under the terms of the Contract for injuries to property or person. Insurance shall be provided by a carrier that has an A.M. Best Rating of not less than “A-,” and a financial rating of VII. The limits of liability shall be no less than:

<table>
<thead>
<tr>
<th>Policy</th>
<th>Minimum Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Workers Compensation</td>
<td>Statutory</td>
</tr>
<tr>
<td>Employer’s Liability Insurance</td>
<td>$500,000.00 each accident</td>
</tr>
<tr>
<td></td>
<td>$500,000.00 disease each employee</td>
</tr>
<tr>
<td></td>
<td>$500,000.00 disease policy limit</td>
</tr>
<tr>
<td>(b) Comprehensive General Liability</td>
<td></td>
</tr>
<tr>
<td>Bodily Injury and property damage</td>
<td>$1,000,000 each occurrence</td>
</tr>
<tr>
<td></td>
<td>$2,000,000 aggregate</td>
</tr>
<tr>
<td>Products/Completed Operations</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>Fire Damage</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>Personal &amp; Advertising Injury</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>(c) Automobile Liability</td>
<td></td>
</tr>
<tr>
<td>Bodily Injury and Property Damage</td>
<td>$1,000,000 each occurrence</td>
</tr>
<tr>
<td>Combined Single Limit</td>
<td></td>
</tr>
</tbody>
</table>

General liability coverages shall be provided by commercial general liability policy on an occurrence basis. The policy date shall predate the Contract. The termination date of the policy shall be no earlier than the termination date of the Contract or later if otherwise specified in the Proposal Documents. Automobile Liability Insurance shall be maintained throughout the term of the Contract to cover owned automobiles; leased, hired, or rented automobiles; employers’ non-ownership liability; medical payments and uninsured motorists. This same coverage is understood to extend to all trucks and motorized equipment.

13. **FAMILIARITY WITH PROPOSED PRODUCTS AND SERVICES**

The Contract is entered into by the College with the understanding that the Contractor, prior to submission of his Proposal, acquainted itself with the requirements of all Instructions to Proposer, Specifications, and other Proposal Documents, and that it has obtained all necessary information for provision of the Products and Services during the term of the Contract. The Contractor shall not at any time after the execution of the Contract set up any claims whatsoever
based upon insufficient data or incorrectly assumed conditions, nor shall the Contractor claim any misunderstanding in regard to the nature, conditions or character of the Products and Services to be provided under the Contract, and Contractor shall assume all risk resulting from any changes in the conditions which may occur during the progress of the work.

14. **HUMAN RELATIONS ACT**

The Pennsylvania Human Relations Act, Act 222 of October 27, 1955, P.L. 744, 43 P.S. §951 et seq., prohibit discrimination because of race, color, religious creed, ancestry, age, sex, national origin, handicap or disability, by employers, employment agencies, labor organizations, contractors and others. Contractor does hereby agree to comply with the provisions of this Act, as amended, which are hereby made part of the Contract. Contractor’s attention is directed to the language of the Commonwealth Non-Discrimination Clause as set forth in 16 Pa. Code §349.101.

15. **ACT 34 CRIMINAL BACKGROUND CHECKS**

Pursuant to Section 1-111 of the Pennsylvania Public School Code of 1949, 24 P.S. §1-111, as the same has been and may be amended from time to time, prior to commencing work under the Contract, Contractor shall submit for any employee or independent contractor who would be working on the College site, pursuant to work contemplated in the Contract, (a) a report of criminal history record information from the Pennsylvania State Police or a statement from the Pennsylvania State Police that the State Police central repository contains no such information relating to that person, (b) a report of federal criminal history record information from the Federal Bureau of Investigation, and (c) a written report from each employee or independent contractor, on the Pennsylvania Department of Education’s standardized form, reporting any arrest or conviction for an enumerated offense. Contractor shall produce the original documentation for each prospective employee or independent contractor of such Contractor prior to employment. Contractor shall not allow any prospective employee or independent contractor on the job site prior to providing the College with the above-referenced criminal history record information for said prospective employee or independent contractor and receiving back from College acknowledgement that the individual is permitted to work on site. As required pursuant to § 1-111, Contractor shall cause its employees and independent contractors to provide written notice of any subsequent arrests or convictions for any enumerated offense with 72 hours after an arrest or conviction. Contractor shall comply with § 1-111, and any and all amendments thereto at Contractor’s sole cost and expense.

16. **CHILD PROTECTIVE SERVICES BACKGROUND CHECKS**

Prior to commencing the work under the Contract, Contractor shall submit for any employee or independent contractor who would be working on the College site, pursuant to any work contemplated in the Contract, an official clearance statement obtained from the Pennsylvania Department of Public Welfare, pursuant to Section 6344 of the Child Protective Services Act, 23 Pa.C.S. §6344(b)(2), as the same has been or may be amended from time to time. Contractor shall not allow any prospective employee or independent contractor on the job site prior to providing the College with the above-referenced clearance statement for prospective employees or independent contractors, and receiving an acknowledgement from the College that
the individual is not named in the Statewide child abuse database as either an alleged perpetrator in a pending investigation, or the perpetrator in a founded or indicated report. Contractor shall comply with all amendments to this Act at Contractor’s sole cost and expense. Contractor shall provide its employees with mandatory child abuse recognition and reporting training per Act 126 of 2012.

17. **ACT 168 EMPLOYMENT HISTORY REVIEW**

Pursuant to § 1-111.1 of the Pennsylvania Public School Code of 1949, 24 P.S. Section 1-111.1, as the same has been or may be amended from time to time, prior to commencing work under the Contract, Contractor shall submit for any employee or independent contractor who would be working on the Owner’s site, pursuant to work contemplated in the Contract, a Pennsylvania Sexual Misconduct/Abuse Disclosure Release form for each of such employee’s or independent contractor’s (a) current employer, (b) former employers considered school entities as defined therein, and (c) former employers where said employee or independent contractor had direct contact\(^1\) with children. Contractor shall provide the Owner with an affidavit affirming that all of the current and former employer’s responses came back with no affirmative responses regarding any of Contractor’s employees or independent contractors contemplated to work on the Owner’s site. Contractor shall not allow, and the Owner will not permit, any employee or independent contractor with any such affirmative responses indicated on any of the Sexual Misconduct/Abuse Disclosure Release forms on the Owner’s site. In any instance where any current or former employee with regard to this paragraph is not responsive and/or fails to return any Sexual Misconduct/Abuse Disclosure Release form regarding any employee or independent contractor, the Owner must approve said employee’s or independent contractor’s placement on the Owner’s site. Contractor shall not allow any prospective employee or independent contractor on the job site prior to providing the Owner with the above-referenced employment history review information for said prospective employee or independent contractor.

18. **WAIVER OF CONSEQUENTIAL AND INCIDENTAL DAMAGES; ECONOMIC LOSS**

A. The Contractor waives claims against the College for consequential and/or incidental damages arising out of or relating to the Contract. This waiver includes, but is not limited to:

(i) Consequential damages incurred by Contractor for principal office expenses including, but not limited to, the compensation of personnel stationed there, for losses of financing, business and reputation, and for loss of profit except anticipated profit arising directly from the Products and Services.

(ii) Incidental damages incurred by Contractor including, but not limited to, costs resulting from stopping performance under the Contract, removing and transporting Contractor’s property (e.g., Contractor’s Products, equipment, supplies and materials) from the

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\(^1\) Direct Contact with Children is defined as “the possibility of care, supervision, guidance or control of children or routine interaction with children.” 24 P.S. §1-111.1(m)
College’s Property, and storing Contractor’s property (e.g., Contractor’s Products, equipment, supplies and materials) at an alternate location.

B. The above waiver is applicable, without limitation, to all consequential and/or incidental damages, due to the termination of the Contract by Contractor or the College.

C. The Contractor shall have no claim or right of recovery of damages against the College for economic loss sustained, in whole or in part, by any act or omission of the College to the extent that such act or omission constitutes a breach of contract. Specifically, and without limiting the generality of the foregoing, Contractor shall have no claim against the College for economic loss based upon any tort, including, without limitation, negligence, negligent misrepresentation or any other tort-based theory of liability.

19. FEES, PERMITS AND CERTIFICATIONS

Contractor, its employees and agents shall secure, at its sole cost and expense, and maintain all necessary permits, licenses and certifications as required by federal, state and local laws, regulations and ordinances, which are legally required prior to and during the work, unless otherwise specified by the College. All costs and fees for same shall be the sole responsibility of the Contractor.

20. TAXES

A. Contractor is responsible for sales taxes and any other applicable taxes related to the Services provided under the Contract.

B. The College is exempt from Federal Excise and State Sales and Use Tax on all tangible personal property purchased or leased by it for its use or consumption. The Contractor shall pay all County, City, State and Federal taxes required by law enacted at the time proposals are received and resulting from the work or traceable thereto, under whatever name levied. Said taxes shall not be in addition to the contract price between the College and the Contractor, as the taxes shall be an obligation of the Contractor and not of College, and College shall be held harmless for same by the Contractor. Exemption certification will be supplied upon request.

21. ALL APPLICABLE LAWS, STATUTES, REGULATIONS AND STANDARDS

A. Contractor shall comply with all applicable federal, state, local and industry statutes, regulations, ordinances, codes and standards. The failure to specifically reference or include said matters in the Contract Documents does not excuse Contractor from compliance with same.

B. The Contractor shall comply with any and all laws, rules, regulations, ordinances, and College policies, applicable to providing the Products and Services contemplated under the Contract. The Contractor, including its employees and agents, shall be responsible for knowing the College’s policies concerning appropriate behavior of persons in its schools, and on its properties including for example, the prohibitions of sexual harassment, alcohol and smoking, and
shall comply with all such policies. In the event any federal, state, local or other governmental body’s laws, rules, ordinances or regulations are revised, changed or amended, or in the event there are revisions, changes or amendments to the College’s policies, the Contractor shall comply with all such revised, changed or amended laws, rules, ordinances regulations or policies, at no additional cost to the College.

C. All Products and Services to be furnished by the Contractor and the Contractor’s working conditions and employment practices shall comply with all applicable state and federal requirements, including, but not limited to, the Occupational Safety and Health Act.

22. CONTRACT TERM

Unless specified otherwise, the initial term of the contract shall be one (1) year. For future contract periods, price increases shall be limited to no more than 3% unless mutually agreed-upon at least 60 days before the renewal term commences. The base price to which any adjustments will be made shall be the prices in effect during the contract term prior to the proposed term.

23. PAYMENT

Invoices received and approved by the College, by the first of the month, will be paid within thirty (30) days. Contractor will be paid in accordance with the foregoing schedule, provided all Products and Services for which payment is requested have been completed in accordance with the Contract and Contractor is in full compliance with all requirements of the Contract. If applicable, Contractor shall submit with its invoices payroll certifications evidencing the number of hours worked per employee (e.g. the employee’s position, number of hours worked per week, building(s) worked in, etc.) and such other information reasonably requested by the College to establish the minimum number of hours are being provided, which payroll certifications shall be in such form as is reasonably satisfactory to the College. If Contractor fails to provide the minimum number of hours required, the College may deduct from Contractor’s monthly payment the total cost of labor and benefits (at the hourly rates set forth on Contractor’s Proposal) for those hours not worked.

24. TIME PERIOD FOR PERFORMANCE OF WORK

A. The time for delivery of Products and Services upon issuance of a purchase order of notice from the College is designated in the Specifications. Time is of the essence in providing all Products and Services required by the Contract.

B. In the event Contractor shall neglect or refuse to provide or complete the Products and Services as required, or any part thereof, or to replace any Products or Services which are rejected, then the College is authorized and empowered to purchase Products and Services in conformity with the Contract from such other party or parties, and in such manner as it shall elect at the expense of the Contractor, or to cancel the Contract; reserving to itself, nevertheless, all rights for damages, including attorney’s fees, legal costs, and additional professional fees, which may be incurred by the College. The foregoing rights and remedies shall be in addition to, and not in limitation of, any other rights and remedies available to the College at law or in equity.
25. **WARRANTY**

A. **Products.**

(i) All Products, whether being physical or virtual, shall be new merchandise (except as agreed by the College), not previously used or recycled merchandise, and all workmanship thereon shall be first class. Each Product, including any labor associated with such Product, shall be guaranteed by Contractor against defects in workmanship and materials for a period of one (1) year from the date such Product was delivered to and accepted by the College, unless a longer period is set forth in the Specifications (the “Warranty Period”).

(ii) During the Warranty Period, Contractor shall promptly remedy, at Contractor’s expense, any defects in such Product, including, without limitation, any damage to College Property, which were caused, in the sole judgment of the College, by defective or inferior Products, workmanship or materials. If these defects are not remedied within five (5) days from notice received, the College shall have the right to replace any and all defective Products and damaged College Property and the Contractor agrees to pay all cost incurred thereby. Said costs may be deducted in whole or in part from the Contractor’s bill if said bill has not been paid in full.

(iii) If a Proposer’s proposed Warranty Period is less than or more than one year, the Proposer must specify the terms of the guarantee along with the price of the Products.

B. **Services.** All Services shall be guaranteed by Contractor against defects in workmanship and materials. During the term, Contractor shall agree to promptly remedy, at Contractor’s expense, any defects in such Services, including, without limitation, any damage to College Property, which were caused, in the sole judgment of the College, by defective or inferior Services, workmanship or materials. Contractor shall re-perform all rejected Services. If these defects are not remedied within five (5) days from notice received, the College shall have the right to have any and all defective Services re-performed by another party and to replace any and all damaged College Property and the Contractor agrees to pay all cost incurred thereby. Said costs may be deducted in whole or in part from the Contractor’s bill if said bill has not been paid in full. Contractor warrants that all Services will be provided as described in the Contract with the College.

C. The foregoing warranties shall be in addition to, and not in limitation of any other warranties available to the College under the Contract Documents or at law or in equity.

26. **DELAY AND EXTENSIONS OF TIME.**

If Contractor is delayed at any time in the progress of the work by any act or neglect of the College, its agents or employees, any separate Contractor employed by College or by changes ordered in the services, labor disputes (excluding labor disputes involving Contractor’s employees), fire, unusual delay in transportation, adverse weather conditions not reasonably anticipated, unavoidable casualties or by any other cause beyond the reasonable control of the Contractor, Contractor’s exclusive remedy shall be an extension of time allowed for completion of the work under the Contract. This extension of time shall not act as an entitlement for damages due and owing the Contractor for said delay. Under no circumstances shall Contractor be entitled
to claim or recover payment, compensation or damages for any delays from any cause whatsoever in the progress of the work, notwithstanding whether such delays be avoidable or unavoidable.

27. **GOVERNING LAW.**

   The Contract shall be governed by the law of the Commonwealth of Pennsylvania, without regard to conflicts of law principles. As between the College and Contractor, any applicable statute of limitations shall commence to run and any alleged cause of action shall be deemed to have accrued as provided by the laws of the Commonwealth of Pennsylvania. The College reserves all rights and privileges applicable to it pursuant to the doctrine of nullum tempus occurrit regi.

28. **CLAIMS AND DISPUTES.**

   Claims, disputes or other matters in question between the parties to the Contract arising out of or relating to the Contract or breach thereof shall be exclusively litigated in the Court of Common Pleas of Montgomery County and shall not be subject to arbitration, except for compulsory arbitration as provided by the applicable rules of civil procedure. Pending resolution of any claim and/or dispute, unless otherwise agreed in writing, Contractor shall proceed diligently with performance of the Contract so as to avoid delay in the schedule of completion of the Project.

29. **WAIVER OF CLAIMS.**

   The acceptance of final payment by Contractor shall constitute a waiver of all claims by Contractor against the College other than those previously made in writing and specifically identified by Contractor as unsettled at the time of application for final payment.

30. **RIGHT TO CONTRACT WITH OTHERS**

   The College reserves the right to contract with other service providers for additional products and services.

31. **ASSIGNMENT AND SUBCONTRACTING**

   The Contractor shall not assign, convey, encumber, subcontract, or otherwise transfer its rights or duties under the Contract, in whole or in part, without the prior written consent of the College. A description of any work the Contractor proposes to subcontract shall be submitted to the College for review and approval along with the name and address of the individual, firm, or corporation that is the proposed subcontractor. This submittal shall also include a list of the key personnel that the subcontractor will assign to the project. All work performed by any subcontractor shall be coordinated by the Contractor and the Contractor will be responsible to the College for all work performed by any subcontractor or special consultant.

32. **NON-APPROPRIATION OF FUNDS**
Any resultant contract shall terminate immediately upon exhaustion of properly appropriated funds should the Board of Trustees fail to appropriate sufficient funds for its continuation. If the College determines, in its discretion, that it lacks adequate funds to pay part or all of the payments for the Products and Services described in the Contract, the College’s obligation under the Contract will terminate as of the date that the funding expires without further obligation to the Contractor.

33. **PROPERTY DAMAGE**

The Contractor shall be responsible for any damage to College Property, buildings, furniture, equipment, systems, information systems, driveways, paving lawns, shrubbery, etc. which is created or caused by its activities, employees, agents or subcontractors.

34. **SUBMISSION OF DOCUMENTS**

Services shall not be started before all insurance documents, background checks and child abuse clearance records have been received by the College.

35. **ENVIRONMENTAL INDEMNIFICATION**

Throughout the term of the Contract, Contractor shall not permit itself or any third party to use, generate, handle, store or dispose of any Hazardous Substances in, on, under, upon or affecting any College property in violation of any federal, state and local laws, rules and regulations regarding the protection of the environment. The Contractor shall abide by all federal, state and local laws, rules and regulations regarding the protection of the environment. The Contractor shall report any violations to the applicable governmental agency and the College. A violation of applicable laws, rule or regulations may result in termination of this Contract. To the fullest extent permitted by law, the Contractor shall indemnify and hold harmless the College, its directors, officers, agents and employees, from and against all claims, damages, losses and expenses, including without limitation attorney’s fees and legal costs, arising out of or resulting from Contractor’s failure to strictly comply with this Section 38 and all federal, state and local laws, rules and regulations governing the protection of the environment. As used herein, the term “Hazardous Substances” shall mean (i) any hazardous or regulated substance as defined by all federal, state and local environmental laws, including, but not limited to, Federal Water Pollution Control Act (33 U.S.C. §§ 1251 et seq.) (“Clean Water Act”), the Resource Conservation & Recovery Act (42 U.S.C. §§ 6901 et seq.) (“RCRA”), Safe Drinking Water Act (42 U.S.C. §§ 300f-j-26), Toxic Substances Control Act (15 U.S.C. §§ 2601 et seq.), Clean Air Act (42 U.S.C. §§ 7401 et seq.), the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. §§ 9601 et seq.) (“CERCLA”), the Emergency Planning and Community Right to Know Act, 42 U.S.C. §§ 11001 et seq. (“EPCRA”), the administrative rules and regulations promulgated under such statutes, or any other similar federal, state or local law or administrative rule or regulation of similar effect, each as amended and as in effect and as adopted as of the date of execution of this Contract, (ii) any other pollutant, contaminant, hazardous substance, solid waste, hazardous material, radioactive substance, toxic substance, noxious substance, hazardous waste, particulate matter, airborne or otherwise, chemical waste, medical waste, crude oil or any fraction thereof, radioactive waste, petroleum or petroleum-derived substance or waste, asbestos,
PCBs, radon gas, all forms of natural gas, or any hazardous or toxic constituent of any of the foregoing, whether such substance is in liquid, solid or gaseous form, or (iii) any such substance the release, discharge or spill of which requires activity to achieve compliance with applicable law.

36. **OWNERSHIP OF DOCUMENTS**

A. All finished or unfinished information or materials (electronic or otherwise), documents, data, studies, surveys, drawings, maps, models, photographs, and reports or other materials prepared by or for the Contractor under any resultant contract shall, at the option of College, become College property and shall be delivered to and remain the property of College upon completion of the work or termination of the Contract. The College shall have the right to use and reproduce the data and reports submitted hereunder, without additional compensation to the Contractor.

B. Any documents provided to the Contractor by the College shall be returned to the College upon request.

37. **ROYALTY AND LICENSE FEES AND COPYRIGHT, TRADEMARK AND PATENT PROTECTION**

A. In submitting its Proposal, the Contractor certifies that there has been no violation of copyrights or patent rights in manufacturing, producing, or selling the Products or Services to be ordered as a result of this Request for Proposals.

B. Unless specified otherwise in the Contract, the Contractor shall pay all royalty and license fees relating to the items covered by the Contract.

C. In the event any third party shall claim that the manufacture, use and sales of the Products or Services offered hereby constitutes an infringement of any copyright, trademark, or patent, the Contractor shall indemnify and hold harmless the College from any cost, expense, damage or loss incurred in any manner by the College on account of such alleged infringement.

38. **CONFIDENTIALITY**

A. In order to facilitate certain discussions, analyses, and activities related to the proposed project, certain information will be disclosed, orally and in writing. All information of any kind disclosed by the College shall be considered confidential and proprietary, regardless of whether it is marked or designated as such, and shall only be used and/or disclosed as appropriate to support the proposed project.

B. The Contractor shall hold and maintain the Confidential Information in strictest confidence for the sole and exclusive benefit of the project. The Contractor shall carefully restrict access to Confidential Information to its employees, contractors and third parties as is reasonably required. Contractor shall not, without prior approval of the College, use for the Contractor's own
benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of the College, any Confidential Information. The Contractor agrees not to disclose the confidential information obtained from the College to anyone unless required to do so by law.

C. The Contractor shall return to the College any and all records, notes, and other written, printed, or tangible materials in its possession pertaining to Confidential Information immediately if the College requests it in writing.

39. ADDITIONAL SERVICES

The College may add to the scope of Products and Services or make changes in the scope of Products and Services to other products and services of a similar nature to those specified in the Specifications of this Request for Proposals as mutually agreed to and at a price mutually agreed upon.

40. NONDISCRIMINATION

If the resultant contract exceeds $10,000, during the performance of the contract, the Contractor agrees as follows:

A. The Contractor will not discriminate against any employee or applicant for employment because of race, religion, color, sex or national origin, except where religion, sex or national origin is a bona fide occupational qualification reasonably necessary to the normal operation of the Contractor. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this nondiscrimination clause.

B. The Contractor, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, will state that such Contractor is an equal opportunity employer.

C. Notices, advertisements and solicitations placed in accordance with federal law, rule or regulation shall be deemed sufficient for the purpose of meeting the requirements of this section.

D. The Contractor will include the provisions of the foregoing subparagraphs A, B and C in every subcontract or purchase order of over $10,000, so that the provisions will be binding upon each subcontractor or supplier.

41. PRECEDENCE OF DOCUMENTS

Unless otherwise noted, the precedence of documents shall be as follows: the Contract, the Request for Proposals and the Contractor’s response to the Request for Proposals.

42. ANTI-TELEFIRE COLLUSION CLAUSE
The College must require that investment advisers, investment service providers and/or investment entities guard against making investments with banks and companies that may have hidden terrorist links.

END OF DOCUMENT
PROPOSAL FORM

Virtual eLearning Platform in Downstream Processing
RFP#02-080315RFP-01

Montgomery County Community College
Purchasing Department
Room 121 College Hall
340 DeKalb Pike, Blue Bell, PA 19422
Attn: Director of Procurement

Date: __________________________

Ladies and Gentlemen:

PROPOSAL SUBMITTED BY:

________________________________________
(Name of Proposing Firm)

________________________________________
(Address)

________________________________________
(Email Address)

________________________________________
(Phone Number)

Deliver unopened Proposals to place and person indicated in the Invitation to Submit Proposal. Deliver this Proposal on or before date and prevailing local time indicated in the Invitation to Submit Proposal. Proposals will be opened and read at time and place indicated in the Invitation to Submit Proposal.

Ladies and Gentlemen:

Having carefully examined the Proposal Documents, including all specifications, the facilities, and all conditions affecting the Products and Services, the undersigned hereby proposes to provide all Products and Services in strict accordance with the Proposal Documents and all Addenda (if any) as indicated below:

ADDENDUM NO. ____ DATED _______ ADDENDUM NO. ____ DATED _______

inclusive, for following fixed fee:
The sum for the Virtual eLearning Platform in Downstream Processing Solution:

(words) dollars ($ )

I agree that if the College desires additional services beyond those specified in the Contract, that I will use commercially reasonable efforts to provide such additional services at a cost not to exceed the hourly rates set forth below. Any additional services shall be by mutual agreement of the College and Contractor and memorialized in writing prior to performance of said services.

<table>
<thead>
<tr>
<th>Per Hour Rate</th>
<th>FY 20__/20__</th>
</tr>
</thead>
</table>

All dollar amounts are stated in United States Dollars.

My Proposal will remain firm for the period of time indicated in the Instructions to Proposers.

The Products and Services shall be completed during the term of the Contract, commencing on ________________, 20___.

This Proposal is submitted in accordance with and subject to all terms and conditions of the Proposal Documents which are incorporated herein by reference and shall be construed to be part hereof, with the same effect as if such were reported at length herein.

When the Proposer is an individual:

WITNESS:

______________________________ (SEAL)
Signature of Individual

Trading and doing business as:

___________________________

When the Proposer is a partnership:

WITNESS:

______________________________
Name of Partnership

______________________________
By: ____________________________(SEAL)
FORM OF NON-COLLUSION AFFIDAVIT

State of ____________________________ : SS
County of ____________________________ :

I state that I am ____________________________ of ____________________________
(Title) (Name of Firm)
and that I am authorized to make this Affidavit on behalf of my firm, and its Owners, Directors
and Officers. I am the person responsible in my firm for the price(s) and the amount of this
Proposal.

I state that:

1. The price(s) and amount of this Proposal have been arrived at independently and without consultation, communication or agreement with any other contractor, Proposer or potential Proposer.

2. Neither the price(s) nor the amount of this Proposal, and neither the approximate price(s) nor approximate amount of this Proposal, have been disclosed to any other firm or person who is a Proposer or potential Proposer, and they will not be disclosed before Proposal opening.

3. No attempt has been made or will be made to induce any firm or person to refrain from bidding on this contract, or to submit a Proposal higher than this Proposal, or to submit any intentionally high or noncompetitive Proposal or other form of complementary Proposal.

4. The Proposal of my firm is made in good faith and not pursuant to any agreement or discussion with, or inducement from, any firm or person to submit a complementary or other noncompetitive Proposal.

5. ____________________________, its affiliates, (Name of My Firm)
subsidiaries, officers, directors and employees are not currently under investigation by any governmental agency and have not in the last three years been convicted or found liable for any act prohibited by State or Federal Law in any jurisdiction, involving conspiracy or collusion with respect to bidding on any public
I state that ____________________________ understands ____________________________

(Name of My Firm)

and acknowledges that the above representations are material and important, and will be relied on by MONTGOMERY COUNTY COMMUNITY COLLEGE in awarding the contract(s) for which this Proposal is submitted. I understand and my firm understands that any misstatement in this Affidavit is and shall be treated as fraudulent concealment from MONTGOMERY COUNTY COMMUNITY COLLEGE of the true facts relating to the submission of Proposals for this contract.

_____________________________________________________________

(Name)

_____________________________________________________________

(Company Position)

SWORN TO AND SUBSCRIBED

BEFORE ME THIS _______ DAY

OF __________________, 20__

_____________________________________________________________

Notary Public

My Commission Expires
INSTRUCTIONS FOR NON-COLLUSION AFFIDAVIT

1. This Non-Collusion Affidavit is material to any contract awarded pursuant to this Proposal. According to Section 4507 of the Pennsylvania Commonwealth Procurement Code, 62 Pa.C.S. § 4507, governmental agencies may require Non-Collusion Affidavits to be submitted together with Proposals.

2. This Non-Collusion Affidavit must be executed by the member, officer or employee of the Proposer who makes the final decision on prices and the amount quoted in the Proposal.

3. Proposal rigging and other efforts to restrain competition, and the making of false SWORN statements in connection with the submission of Proposals are unlawful and may be subject to criminal prosecution. The person who signs the Affidavit should examine it carefully before signing and assure himself or herself that each statement is true and accurate, making diligent inquiry, as necessary, of all of persons employed by or associated with the Proposer with responsibilities for the preparation, approval or submission of the Proposal.

4. In case of a Proposal submitted by a joint venture, each party to the venture must be identified in the Proposal Documents, and an Affidavit must be submitted separately on behalf of each party.

5. The term “Complementary Proposal” as used in the Affidavit has the meaning commonly associated with that term in the bidding process, and includes the knowing submission of Proposals higher than the Proposal of another firm, any intentionally high or noncompetitive Proposal, and any other form of Proposal submitted for the purpose of giving a false appearance of competition.

6. Failure to file an Affidavit in compliance with these instructions may result in disqualification of the Proposal.

7. A Proposer’s statement that it has been convicted or found liable for any act prohibited by Federal or State Law in any jurisdiction involving conspiracy or collusion with respect to bidding on any public contract within the last three (3) years does not prohibit a government agency from accepting a Proposal from or awarding a contract to that Proposer, but it may be grounds for administrative suspension or debarment in the discretion of the government agency under the rules and regulations of that agency or, in the case of a government agency with no administrative suspension or debarment regulations or procedures, may be grounds for consideration on the question of whether the agency should decline to award a contract to that person on the basis of lack of responsibility.

END OF DOCUMENT
FORM OF AGREEMENT BETWEEN COLLEGE AND CONTRACTOR

MONTGOMERY COUNTY COMMUNITY COLLEGE

This contract (“Contract”) is entered into by and between the Montgomery County Community College, a public College in the Commonwealth of Pennsylvania (hereinafter “College”) and ____________________________ (hereinafter “Contractor”).

WITNESSETH

WHEREAS, the College desires to enter into an agreement for Virtual eLearning Platform in Downstream Processing (the “Products and Services”).

WHEREAS, the College and Contractor agree that it shall be the primary obligation of the Contractor to operate its affairs so that the College will be assured of Contractor’s continuous and reliable service.

NOW, THEREFORE, in consideration of the mutual promises herein contained and intending to be legally bound hereby, the parties hereto agree as follows:

1. **Term:** The Contractor agrees to provide the College with the Products and Services commencing ________________, 20___ and ending ________________, 20____, subject to the termination provisions set forth in the Contract. For future contract periods, price increases shall be limited to no more than 3% unless mutually agreed-upon at least 60 days before the renewal term commences. The base price to which any adjustments will be made shall be the prices in effect during the Contract term prior to the proposed term. The continuation of this Contract is contingent upon satisfactory performance by the Contractor. If the provision of Products and performance of the Services are not acceptable, this Contract may be terminated by the College at no additional cost to the College. The College shall be the sole determiner of the quality of Products and Services and whether they are satisfactory.

2. **Description of Services:** Contractor agrees to and shall furnish the Products and Services, as a fee for service model, in accordance with this Contract, the Proposal submitted by Contractor (but excluding any exceptions to College’s RFP, unless expressly set forth in this Section 2 as being accepted by College) and other Contract Documents.

3. **Payment of Services:** During the term of this Contract, Contractor shall invoice the College based on the completion of mutually agreed upon milestones. Payment shall be made by the College within thirty (30) days of receipt of Contractor invoices as set forth in the Instructions to Proposer. Payment shall only be rendered upon the successful submission of an invoice to the College by the Contractor no later than the first day of the month. All invoices must be submitted in accordance with the College’s instructions and must contain any or all information requested by the College. Invoices not submitted by the Contractor on or before the date as specified shall be carried by the Contractor until the next billing date at no additional cost to College. If applicable, Contractor shall submit with its invoices payroll certifications evidencing
the number of hours worked per employee (e.g. the employee’s position, number of hours worked per week, building(s) worked in, etc.) and such other information reasonably requested by the College to establish the minimum number of hours are being provided, which payroll certifications shall be in such form as is reasonably satisfactory to the College. If Contractor fails to provide the minimum number of hours required, the College may deduct from Contractor’s monthly payment the total cost of labor and benefits (at the hourly rates set forth on Contractor’s Proposal) for those hours not worked. The Contractor’s records and documentation supporting such invoices shall be made available to College upon reasonable request. The Contractor agrees to retain all records, documents and support materials relevant to the contract for a period of five years following final payment.

4. **Insurance:** Prior to the commencement of the provision of Products and Services and throughout the entire term of this Contract, Contractor shall maintain insurance of the type and in the amounts set forth in the Instructions to Proposer.

5. **Assignment and Subcontracting:** The Contractor shall not sublet, sell, transfer, assign, or otherwise dispose of the Contract, or any portion thereof, or of its right, title, or interest therein without the prior written consent of the College which consent may be withheld at the College’s sole discretion. No subcontract shall be made with any other party for furnishing any of the Products and Services to be provided in accordance with this Contract without the prior written consent of the College, which consent may be withheld at the College’s sole discretion.

6. **Independent Contractor:** Contractor understands that in performing this Contract, Contractor is acting in the capacity of an independent contractor, and the Contractor shall not be an agent, servant, partner nor employee of the College. Contractor shall be solely responsible to pay its own federal, state and local income taxes for its employees, salaries, social security payments, and any and all other payments incurred by Contractor in the performance of this Contract, as well as perform all necessary legal requirements pertaining to employment. None of the benefits provided by the College to its employees, including, but not limited to, workers’ compensation insurance, disability insurance, medical insurance, and unemployment insurance are available from the College to Contractor and/or any of Contractor’s agents, servants, or employees. Contractor has no authority to assume or create any obligations or responsibility, express or implied, on behalf of or in the name of the College, or to bind the College in any way whatsoever.

Contractor hereby agrees that the Products and Services to be performed under this Contract will be performed entirely at Contractor’s risk, and Contractor assumes all responsibility for the subject matter of this Contract. Contractor shall be solely responsible for its acts during the provision of Products and performance of the Services set forth in this Contract.

Contractor hereby agrees that in the provision of Products and the performance of the Services required under this Contract, Contractor has full and sole responsibility for compliance with all federal, state and local laws, regulations and ordinances.

7. **Indemnification:** To the fullest extent permitted by law, the Contractor shall indemnify and hold harmless the College, its directors, officers, agents and employees, from and against all
claims, damages, losses and expenses, including without limitation attorney’s fees and legal costs, arising out of or resulting from the Contractor’s performance of the Contract, including, without limitation claims, damages, losses or expenses attributable to bodily injury, sickness, disease or death, or to injury to or destruction of property, including loss of use resulting therefrom, caused in whole or in part by acts or omissions or negligence of the Contractor, a subcontractor, anyone directly or indirectly employed by them or for anyone for whose acts they may be liable, regardless of whether or not such claim, damage, loss or expense is caused in part by the College. Contractor further agrees to indemnify, save and hold the College, and its directors, officers, agents, and employees harmless from and against any and all claims brought by the agents, workers, servants, or employees of Contractor for any alleged negligence or condition caused or created, in whole or in part, by the College. The indemnification obligations under this paragraph shall not be limited by a limitation on amount or type of damages, compensation or benefits payable by or for the Contractor or a subcontractor under workers’ or workmen’s compensation acts, disability benefit acts or other employee benefit acts. Further, nothing in this indemnification provision is intended to waive or extinguish the immunity protections of the College, its agents or employees as set forth in the Pennsylvania’s Political Subdivision Torts Claims Act. Contractor’s indemnity obligations shall be in addition to any insurance requirements under the Contract and any other indemnity obligations under the Contract, and shall survive the expiration or earlier termination of the Contract.

8. **Release:** Contractor hereby releases the College, its directors, officers, agents, workers, servants and employees from any and all matter of liability whatsoever, whether it be in law or in equity, as to any kind and all kinds of damages, which shall include, but not be limited to, personal injury and damage to personal property, resulting to the Contractor, its agents, servants, or employees in the provision of Products and performance of the Services described herein.

9. **Termination Provisions; Partial Cancelation:**

   A. At any time during the term of this Contract, the College shall have the unilateral right to terminate Contractor for “cause” (as defined below) effective immediately upon notice to Contractor. For purposes of this Contract, “cause” shall mean:

   i. Contractor breaches, neglects or fails to diligently perform, to the satisfaction of the College, any or all of Contractor’s responsibilities under this Contract;

   ii. Contractor commits an act of dishonesty or breach of trust, or acts in a manner adverse or injurious to the interest of the College;

   iii. Contractor’s act or omission results in or is intended to result directly in gain to or personal enrichment of Contractor at the College’s expense;

   iv. Contractor violates or breaches any of the provisions of this Contract;

   v. Contractor or any of Contractor’s employees, agents, or servants are indicted for or convicted of a felony or any crime involving larceny, embezzlement or moral turpitude; or
vi. Contractor becomes insolvent, makes an assignment for the benefit of creditor(s), files or has filed against Contractor a petition for relief or other proceeding under Federal bankruptcy laws, state insolvency law, or is assessed, or administered in any type of creditor’s proceeding.

B. Notwithstanding anything contained in subsection A to the contrary, upon ten (10) days written notice to Contractor, the College may, without cause and without prejudice to any other right or remedy, elect to terminate the Contract. Upon receipt of written notice from the College of such termination, Contractor shall cease operations as directed by the College in the notice; take actions necessary, or that the College may direct, for the protection and preservation of the work; and except for work directed to be performed prior to the effective date of termination stated in the notice, terminate all existing subcontracts and purchase orders and enter into no further subcontracts and purchase orders. In case of such termination, where Contractor is without fault, Contractor shall be entitled to receive payment from College for all work satisfactorily performed prior to termination.

10. Entire Agreement, Caption, Counterparts and Modifications: This Contract, together with the documents incorporated by reference in Section 18 of this Contract, contains the entire agreement between the parties hereto with respect to the transactions contemplated hereby, and supersedes all previous written or oral negotiations, commitments, agreements and writings. The captions in this Contract are for the convenience of reference only, and do not form a part hereof, and do not in any way modify, interpret or construe the intention of the parties. This Contract may be executed in any number of counterparts. Each counterpart shall be deemed to be an original instrument, and all such counterparts together shall constitute but one instrument. This Contract may only be modified in writing and signed by all of the parties. Capitalized terms used in this Contract but not otherwise defined herein shall have the meaning ascribed to such terms in the Instructions to Proposers or Specifications.

11. Governing Law, Jurisdiction and Venue: This Contract shall be construed and interpreted and its validity shall be determined in accordance with the laws of the Commonwealth of Pennsylvania, without regard to conflicts of law principles. Jurisdiction and venue for any disputes arising in connection with this Contract shall lie solely with the Court of Common Pleas of the Commonwealth of Pennsylvania, in and for the County of Montgomery. All parties hereto hereby submit themselves to the exclusive jurisdiction and agree to accept service of any court process, order or other document by certified mail in lieu of personal service.

12. Notices: Any notice required to be given hereunder shall be given in writing, and shall be served in person, or deposited in the form of a written notice in the United States mail and sent by registered or certified mail with postage charges prepaid, or sent by national overnight delivery service, including, but not limited to, Federal Express or through an electronic delivery system, such as telex or fax, properly addressed and directed to the party to receive the same, at the following addresses or such other address as may hereafter be substituted therefore by notice in writing thereof:

If, to the College:
Montgomery County Community College  
Vice President for Finance & Administration  
340 DeKalb Pike  
Blue Bell, PA 19422

With a copy to:

Marc B. Davis, Esquire  
Fox Rothschild LLP  
Ten Sentry Parkway, Suite 200  
Blue Bell, PA 19422

If to the Contractor:

_______________________  
_______________________  
_______________________

Notice shall be deemed given on the earlier of the date of receipt or the second business day after having been mailed in accordance with this Section. The Contractor agrees to notify College immediately of any change of legal status or of address.

13. **Invalidity:** The invalidity of any one or more of the words, phrases, sentences, Sections or subsections contained in this Contract shall not affect the enforceability of the remaining portions of this Contract or any part thereof, all of which are inserted conditionally on their being valid in law. In the event that any one or more of the words, phrases, sentences, sections or subsections are found to invalid or unenforceable, this Contract shall be read as is if such offending provisions had not been inserted, and if such invalidity shall be caused by the length of any period of time set forth in any part hereof, such period of time shall be considered to be reduced or increased, as necessary, to a period to time set forth in any part hereof, such period of time shall be considered to be reduced or increased, as necessary, to a period which would cure such invalidity.

14. **Binding Effect:** This Contract shall be binding upon and insure to the benefit of the parties hereto and their respective successors and permitted assigns.

15. **Waiver:** The waiver by a party of any term, covenant, obligation, or condition herein contained shall not be deemed to be a waiver of any subsequent breach of the same or waiver of any obligation or condition herein contained. No covenant, term, obligation or condition of this Contract shall be deemed to have been waived by the College, unless such waiver be in a written notice to Contractor executed by the College.
16. **Construction:** For purposes of this Contract, the neuter shall include the masculine and the feminine, the masculine shall include the feminine, the feminine shall include the masculine, the singular shall include the plural, and the plural shall include the singular, as the context may require.

17. **Remedies:** The rights and remedies of the College contained herein shall not be exclusive and are in addition to any rights and remedies provided under the law or in equity.

18. **Incorporation by Reference:** The terms and conditions of the following documents, if checked, are hereby incorporated herein by reference and made a part thereof:

   a. Invitation to Submit Proposal ____________________________________ X
   b. Instructions to Proposers________________________________________ X
   c. Proposal Documents____________________________________________ X
   d. Specifications_________________________________________________ X
   e. Addenda ______________________________________________________ X
   f. Non-Collusion Affidavit_________________________________________ X
   g. Campus Map____________________________________________________ X
   h. Contractor’s Proposal____________________________________________ X

   (excluding any exceptions to the College’s RFP, unless the College has expressly acknowledged and incorporated such exceptions in Section 2 above.)

   IN WITNESS WHEREOF, the parties have hereunto set their hand and seal as of the date first above written.

   MONTGOMERY COUNTY
   COMMUNITY COLLEGE

   Attest: ___________________________  By: ___________________________
   Name: ___________________________  Name: ___________________________
   Title: _____________________________  Title: ___________________________

   Contractor

   ___________________________

   (CORPORATE SEAL)
SPECIFICATIONS

A. Purpose: This document details the proposal for the design and development of a virtual educational platform that includes learning modules in downstream processing. These virtual modules are to be developed to augment the global biomanufacturing curriculum and to advance biomanufacturing educational initiatives. This project and its development are supported by DOL TAACCCT c3bc federal grant funds.

The purpose of this Request for Proposal (RFP) is threefold:
1. Provide background information on the Department of Labor (DOL) Trade Act Assessment (TAA) Community College Consortium for Bioscience Credentials (c3bc) grant;
2. Detail the rationale for the development of interactive, simulation-based downstream processing modules for biomanufacturing education; and
3. Request additional details on the estimated costs and timelines for the design and development of these virtual educational modules from interested service providers.

B. Background: The Community College Consortium for Bioscience Credentials (c3bc) is a multistate consortium of 12 Community Colleges funded by the Department of Labor (DOL) that has several aims which include:
1. Harmonize core skills and competencies across the biosciences, including biotechnology, biomanufacturing, and medical devices;
2. Expand and improve the delivery of education and career training programs at the Community College level; and
3. Assist grant participants to obtain employment in high-wage, high-skill occupations, such as biotechnology and biomanufacturing.

C. Purpose/Rational: Virtual modules in downstream processing are to be developed as a fee-for service to augment the global biomanufacturing curriculum and to advance biomanufacturing education. These educational elements will present interactive learning experiences in downstream processing to benefit biomanufacturing trainees and student participants across the c3bc and the nation. This curriculum development project is supported with DOL federal grant funds to advance the TAACCCT c3bc initiative.

This product is funded by a grant awarded by the U.S. Department of Labor’s Employment and Training administration. The product is created by the grantee and does not necessarily reflect the official position of the U.S. Department of Labor. The Department of Labor makes no guarantees, warranties, or assurances of any kind, express or implied, with respect to such information, including any information on linked sites and including, but not limited to, accuracy of the information or its completeness, timeliness, usefulness, adequacy, continued availability, or ownership.
D. **Scope of Work:** In support of the development of the virtual modules in downstream processing, the service provider will provide/perform the following services, materials, and capabilities (*but not limited to*):

1. **Develop a rich and immersive e-learning environment that renders industrial biomanufacturing processes and presents interactive learning experiences to biomanufacturing trainees and student participants.**
   a. Provide a graphical interface, learning materials, and a technology solution, such as a content management system, to present the bio-manufacture, purification, and final production of monoclonal antibodies (mAb) from mammalian cells (see description of Process Workflow in the supplemental section, Appendix B)
   b. Provide a medium level of interactivity (multi-variant input levels) overall with 4 areas of high interaction (robust graphical interface) and 3-4 areas for lower levels of graphical interface
   c. With the SME’s, develop approximately 45-60 minutes of e-learning in total

2. **Provide an open, portable, technology platform that provides a browser-based user interface and manages the learning environment. This could be a ready-made solution, such as CourseSites or another technology. The platform will have the following capabilities:**
   a. Provide a portal/webpage (with domain name / URL) as point of entry
   b. Provide login/registration and curation
   c. Track participant’s progress in downstream processing educational modules
   d. Collect and store participant progress and status
   e. Provide the capability for a decision tree/s
   f. Provide the capability for a single final assessment and curation
   g. Enable interactivity simulations for key and multivariable outcomes
   h. **Legacy-** the technology must be **self-sustaining** and require **no additional costs** to maintain beyond the initial fee-for-service contract

3. **Collect data from participants:** The platform will facilitate the collection of specific information (contact/email details, assessment status, and assessment results) from participants

4. **Curate data from participants and assessments:** The platform will facilitate the storage and recall of specific information (contact details, assessment progress, and assessment results) from participants

5. **Develop a user-friendly interface:** Design and develop an open, portable, and user-friendly platform interface (preferably browser-based solution) for participants/users.

6. **Provide a technology solution with free ongoing-support and maintenance:** The technology solution is to provide free support in the form of access to domains, server, hosting, security patches, software updates, and on-going support services as necessary for the learning modules to function on an ongoing basis.
E. Proposed schedule of Implementation

**The College retains the right to adjust or revise the referenced implementation schedule.**

<table>
<thead>
<tr>
<th>Deliverable Number with Description</th>
<th>Estimated Invoice Date and Total Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Provide an overview of the manufacturing facility and of the workflow processes / equipment</td>
<td>October 30, 2015</td>
</tr>
<tr>
<td>#2 Render instructional design elements and visualizations for major elements of equipment</td>
<td>Billing Amount: $ (15% of total)</td>
</tr>
<tr>
<td>#3 Provide an implementation strategy for incorporation of instructional learning elements within the workflow</td>
<td></td>
</tr>
<tr>
<td>#4 Provide instructional design visualizations and detail the purification of Ab IgG from capture chromatography through diafiltration:</td>
<td>December 30, 2015</td>
</tr>
<tr>
<td>• Detail the units, platforms, column, filters and processes</td>
<td>Billing Amount: $ (25% of total)</td>
</tr>
<tr>
<td>• Provide detailed visualization of an affinity-A purification process with elution</td>
<td></td>
</tr>
<tr>
<td>• Detail filtration of the product for concentration / buffer exchange</td>
<td></td>
</tr>
<tr>
<td>#5 Incorporate instructional learning elements as the equipment/processes are developed for the workflow</td>
<td></td>
</tr>
<tr>
<td>#6 Provide instructional design visualizations and detail the purification of Ab IgG from intermediate chromatography through final filtration stages</td>
<td>February 28, 2016</td>
</tr>
<tr>
<td>• Detail the units, platforms, column, filters and processes, including cation exchange</td>
<td>Billing Amount: $ (25% of total)</td>
</tr>
<tr>
<td>• Provide detailed visualization of cation exchange purification processes and an overview of anion exchange</td>
<td></td>
</tr>
<tr>
<td>• Detail the equipment and processes up to final formulation</td>
<td></td>
</tr>
<tr>
<td>• Detail QC biochemistry with HPLC</td>
<td></td>
</tr>
<tr>
<td>#7 Incorporate instructional learning elements as the equipment/processes are developed for the workflow</td>
<td></td>
</tr>
</tbody>
</table>
F. Requirements:

1. **Technical requirements.** An open, portable, technology solution that is compliant with the requirements of IT department at MCCC and has the following capabilities:
   a. An adaptable and flexible *open platform* that is compatible with various PC’s and/or tablet devices (Mac or Android)
   b. Provide for a portal/webpage as point of entry
   c. Enable a browser-based user interface
   d. Provide for a user login/registration and curation
   e. The ability to track participant’s progress / status in the educational modules
   f. Provide for a final assessment and curation
   g. A platform compatible with common internet browsers such as Internet Explorer, Firefox, and Chrome
   h. Access to a domain, domain name, and free server / hosting services

2. **Educational requirements.** A platform that:
   a. Provides a stimulating and visually appealing learning environment; and
   b. Supports the learning objectives and outcomes with texted material and other educational aids. Refer to “Appendix A” for learning objectives.
   c. Provides for a single assessment with certificate of completion of said assessment and/or the potential for a digital badge.

3. **Project requirements**
   a. A fee-for-service contract
   b. Receipt of original learning outcomes and curriculum content from SME’s
   c. Development of a visually appealing graphical environment within industrial biomanufacturing based upon guidance detailed in the ‘Process Workflow’ outlined in “Appendix B”
d. Compliance with the DOL TAA federal grants and MCCC reporting requirements, standard, data security, privacy, policy, etc.
e. Commitment to deliver products and services as described within the timeframes of the RFP
f. Familiarity with associated other biomanufacturing resources such as Biomanufacturing.org and ncbionetwork.org/educational-resources
g. Participation in weekly meeting and bi-monthly reports to stakeholders

G. Frequently asked questions for the implementation of the virtual learning modules in Downstream Processing:
1. Dependencies - What is the vendor dependent upon to deliver the offering (software, hosting, etc.)? The vendor is to provide a 3rd party solution for server/hosting/database and a webpage location (potentially Biomanufacturing.org)
2. Hosting/Reliability – Where will the learning module/s be housed/located and what is the anticipated reliability? The virtual learning module/s will make use of a cloud-based solution with a high level of reliability. CourseSites by Blackboard is one such cloud-based LMS solution.
3. Implementation - Who would be responsible for implementation? The representatives of the BMF HUB College (working alongside with the service provider) would be responsible initial implementation – listing the educational materials on a webpage such Biomanufacturing.org with a unique URL pointing to the tech cloud-based solution. Continued maintenance (hosting/server/database) is to be self-sustaining.
4. Integration – Are there limitations to integrate this technology solution with current systems? The use of a broad-based, more universal solution would diminish the risk of integration with current systems.
5. Functionality – What is the expected reporting functionality? Users would be expected to register/login, have their progress tracked, and be issued a credential upon completion. Beyond issuance of the credential, no additional reporting is anticipated.
6. Training – What training is necessary for the user and/or the College? No initial training is anticipated beyond any formal/informal training in downstream processing.
7. Customer Support – What level of customer support is anticipated? After initial implementation, the tech solution is to be self-sustaining and no customer support is anticipated and/or budgeted.
8. Upgrades – How will the platform be maintained and upgraded? The 3rd party solution for server/hosting/database will provide upgrades as necessary (free of charge) to maintain the platform.

H. Reporting and communication: In support of this work, it is recommended that several types of communications be conducted to monitor progress and resolve project challenges. These include (but are not limited to):
a. The service provider be available via electronic and phone communications
b. Weekly progress meetings be held among project representatives from both MCCC and the service-provider development team.
c. Three progress reports will be submitted by the service provider on the 15th calendar day for the preceding 2-month period. These status reports are to include the following information:
   i. A milestone chart detailing the preceding two months accomplishments
   ii. A description of any challenges/difficulties encountered during the current reporting cycle with root-cause delay details and current solutions
   iii. A listing of significant tasks to be completed during the next reporting cycle
   iv. A summary of funds: spent during the last reporting cycle, spent to date, and appropriate amount to be spent during the next reporting cycle
   v. Additional information as appropriate and necessary to detail the project

I. Change control. The Service provider and MCCC shall utilize a change control process to manage project alterations. To maintain project timelines, change controls will be limited to no more than three modifications in total and will include:
   1. Documentation: A change request must be documented in writing with detailed descriptions of potential alteration and explanations/rational for modifications. The process change will include an estimate of the activities/modifications, impact to costs, schedules, scope, and outcomes.
   2. Submission and tracking: A change request must be submitted to the project Director, logged, and tracked in the management log. Until the process change is accepted and implemented, work will continue on the project under the original agreement.
   3. Review: A change request must be reviewed and accepted by the project Director before any changes to the original agreement are implemented and new activities are initiated. Any changes will be recorded in the management log and signatures provided as acceptance of any changes/modifications.
   4. Implementation: Once accepted, new activities may begin as agreed upon.

END OF DOCUMENT
Appendix A – Educational Objectives

**Learning Objectives and Outcomes.** Upon successful participation in- and completion of the virtual learning modules, the user will be able to:

<table>
<thead>
<tr>
<th>Learning Outcomes</th>
<th>Learning Activities</th>
<th>Evaluation Methods</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the overall elements of equipment and processes involved in the biomanufacturing process for a typical monoclonal antibody-based therapeutic, starting with the bioreactor harvest pool, to pre-formulation, and finishing with QC testing of the drug product.</td>
<td>Virtual biomanufacturing learning modules; Textbook; Tours of local BMF facilities</td>
<td>Completion of the virtual module’s assessment - ‘Check your knowledge’</td>
<td>Reference textbook: <em>Introduction to Bio manufacturing</em>; NBC2, 1st Edition, November 2012; Lab scale SOP’s</td>
</tr>
</tbody>
</table>
| Define the specific methods, in-process tools and materials, and physical / chemical mechanisms used in the downstream process, including:  
  – harvest of the product by continuous centrifugation  
  - clarification of the bioreactor harvest by depth filtration  
  – affinity (capture) chromatography  
  – diafiltration and sterile filtration of the product at various stages in the downstream process  
  – intermediate purification, IEX  
  – polishing chromatography, IEX  
  – sterile filtration of the product prior to final formulation | Virtual biomanufacturing learning modules; Textbook; Tours of local BMF facilities | Completion of the virtual module’s assessment - ‘Check your knowledge’ | Reference textbook |
| Describe a test analytical method, HPLC, used to provide product specifications for a typical monoclonal antibody-based therapeutic. | Virtual biomanufacturing learning modules; Textbook | Completion of the virtual module’s assessment. | Reference: Chapter 9 with HPLC (purity / heterogeneity) |
| During the manufacturing process of pharmaceutical agents, awareness and use of major cGMP regulations and documentation strategies, such as SOPs, batch records, and training records. | Virtual biomanufacturing learning modules; Textbook | Completion of the virtual module’s assessment. | Reference SOP’s, batch records, and training records |

**Learning Credentials:**
Certificate with potential for electronic badge
Appendix B - Process Workflow

Overall workflow for downstream processing in the biomanufacture, purification, and final production of a monoclonal antibodies (mAb) from mammalian cellular culture.

A. **Overview**: Develop a fly-in with Graphical User Interface (GUI) that presents a visual representation of a manufacturing facility with all of the appropriate industrial equipment.

B. **Process workflow elements**: graphically represent industrial biomanufacturing equipment and processes based upon the following components of downstream processing (see below). Note, areas for high level of user interactivity and Robust Graphical Interface (RGI) are noted as *RGI.

<table>
<thead>
<tr>
<th>Process Workflow</th>
<th>Purpose / Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvest by continuous centrifugation from a hold tank</td>
<td>Sedimentation-based clarification to remove cells and larger contaminants/debris</td>
</tr>
<tr>
<td>Depth filtration (API passes through as filtrate)</td>
<td>Use of microfiltration to clarify the feed and remove larger contaminants/debris</td>
</tr>
<tr>
<td>Sterile Filtration</td>
<td>Use of nanofiltration to remove small debris and any microbial contamination</td>
</tr>
<tr>
<td>Holding Tank (5-10K Liter Unit)</td>
<td>Storage until capture chromatography</td>
</tr>
<tr>
<td>Sterile Filtration</td>
<td>Use of nanofiltration to remove small debris and any microbial contamination</td>
</tr>
<tr>
<td>Affinity-A Capture Chromatography *RGI</td>
<td>Initial purification and concentration step with Protein A</td>
</tr>
<tr>
<td>Low-pH Hold/Elution (pH 2.5-4)</td>
<td>Dedicated virus removal/clearance</td>
</tr>
<tr>
<td>Diafiltration (TFF) *RGI</td>
<td>Concentration/Buffer exchange</td>
</tr>
<tr>
<td>Sterile Filtration</td>
<td>Removal of small debris, any microbial contamination</td>
</tr>
<tr>
<td>Intermediate Chromatography *RGI</td>
<td>Additional purification using Cation IEX; removal of isoforms/leached resin</td>
</tr>
<tr>
<td>Diafiltration (TFF)</td>
<td>Concentration/Buffer exchange</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Polishing</td>
<td>Additional purification using Anion IEX; removal of virus, other micro contaminants;</td>
</tr>
<tr>
<td>Chromatography *RGI</td>
<td></td>
</tr>
<tr>
<td>Diafiltration (TFF)</td>
<td>Concentration/Buffer exchange</td>
</tr>
<tr>
<td>Sterile Filtration of bulk fill prior to final formulation</td>
<td>Removal of any nanoparticle contamination and viral clearance prior to final release</td>
</tr>
<tr>
<td>Sample for testing by HPLC (purity/heterogeneity)</td>
<td>QC Biochemistry testing prior to final formulation and release of the drug product</td>
</tr>
</tbody>
</table>

**Appendix C - Resources:**

**Textbook:** *Introduction to Biomanufacturing* Nov 2012  
Chapter 9: Quality Control Biochemistry  
Chapter 10: Upstream processing  
Chapter 11: Downstream processing

**Purification** – refer to the GE Healthcare website for both the *Affinity Chromatography Handbook* and the *Antibody Purification Handbook* for more detailed information:  

**Website:** [http://www.ncbionetwork.org/educational-resources](http://www.ncbionetwork.org/educational-resources)