Toward a Standardized Curriculum for Development of the Vaccine Manufacturing Workforce

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 Highlight the need for a standardized curriculum for the vaccine manufacturing workforce.

 Discuss the importance of industry/academia collaborations in workforce development efforts.
The US Department of Labor identifies important workforce issues in the biotech/ biomanufacturing sectors as:

* Recruitment
* Basic education, and
* Task-oriented training
A challenge to the biomanufacturing industry is finding experienced technicians with specialty skills that align with a highly regulated work environment such as:

- cGMPs and validation.
- Quality control and quality assurance.
- Regulatory requirements.
Academic institutions have extensive expertise in educating students in specific disciplines. Once a graduate arrives in a job, however, it is inevitable that he/she will need additional task oriented training in areas not covered in the university program.
Recruitment is especially challenging when an employee's knowledge base must include both regulatory and scientific knowledge.

This knowledge base creates a demand for non-traditional task-oriented training programs with high-quality content.
Skill Standards

- Communication
- Basic Laboratory
- Problem Solving
- Instrumentation Maintenance
- Safety and Health Issues
- Quality Control
- Quality Assurance

- **Upstream Processing**
- **Downstream Processing**

*These skills may be common or required but are not universal*
**Biomanufacturing**

- **Cells**
- **Media**
- **Reactor**

**Conversion Stage**

- *Dissolved oxygen*
- *Agitation*
- *pH*
- *Aeration*
- *Temp*
- *Asepsis*

**Product Separation & Purification**
Follow SOPs, in accordance with a GMP environment to perform the growth and the infection of cells/eggs

Tasks include:

- Cell line preparation
- Media preparation
- Bioreactor set-up
- Growth parameters
- Monitor and control
- Harvest & Waste Disposal
- Egg handling
- Virus injection
- Incubation
- Harvest
- Waste disposal

Upstream Processing
Follow SOPs, in accordance with a GMP environment to perform purification and formulation steps. This is a major part of the vaccine manufacturing process and the most expensive.

**Tasks include:**

- Ultra and cross flow filtration/concentration.
- Virus inactivation & detergent splitting.
- Formulation/Adjuvants/Preservatives.
- Fill and finish.
- Records maintenance to comply with regulatory requirements and in-process testing.
Universities, as teaching institutions, must extend themselves and link with the biotechnology industry and state and federal agencies to create a well-trained workforce.

Close cooperation between universities and industry can successfully address the industry's need for the development of programs to fill knowledge gaps in entry-level personnel.

- Undergraduate curriculum redesign - Long-term.
- Short, intensive training programs - Short-term
Vaccine Manufacturing Industry

Short, Intensive Workforce Training

Academic Institutions

Equipment Manufacturing Industry
Why are collaborative efforts necessary?

- Rapidly changing, sophisticated technologies that frequently require equipment that is continually being updated.

- High cost of equipment, disposables and assay kits required for training.

- Limited number of available expert trainers for certain technologies.

- Scientists from industry can help academic institutions identify skills, techniques, courses and course content that would make new graduates attractive to industry.
When industry provides cutting-edge laboratory resources and academia provides the teaching, hands-on training is affordably accessible for the rapidly growing population of biomanufacturing professionals.
What is Needed

Strong vaccine biomanufacturing training programs.

Delivered by highly trained professionals.

Must be able to meet the demands of the rapidly growing vaccine manufacturing industry.

The answer: Structured Outreach programs with standardized curriculum.
Implications of a Standardized Curriculum

- Increased program efficiency.
- Enables iterative program development.
- Establishes certification criteria.
- Informs stakeholders through research.
Example of a successful collaboration

- Utah State University Biomanufacturing Training Programs:
  - Short term intensive, innovative and hands-on
  - Significant participation by industry:
    - New Brunswick Scientific Co.
    - Thermo Fisher
    - Applikon Biotechnology
    - Broadly James
    - GE Healthcare
    - Pall Filtration
  - Industry Consultants
  - On-site programs are available- Internationally.
Thank you

BARDA/USU Influenza Vaccine Manufacturing Training Program 2011 Participants