

This copy is for your personal, non-commercial use. For high-quality copies or electronic reprints for distribution to colleagues or customers, please call +44 (0) 20 3377 3183

Printed By **Joanne Eglovitch**

Workforce Of The Future Initiative Aims To Close Skills Gap In Biopharmaceutical Industry

22 Jun 2020 | **NEWS**

by **Joanne S. Eglovitch** | joanne.eglovitch@informa.com

Executive Summary

The biopharmaceutical industry is expanding its presence on college campuses to address a shortage of workers proficient in advanced manufacturing, cell and gene therapies and combination products. Executives say that not having enough of these skilled workers keeps them up at night.



WORKFORCE OF THE FUTURE INITIATIVE LAUNCHES TO ADDRESS SKILLS GAP

Source: Shutterstock

The biopharmaceutical industry is collaborating with academia in an initiative launched last year in the hope that by teaching university classes, industry experts can help to fill a widening workforce gap in cell and gene manufacturing, continuous manufacturing and combination products.

There is a shortage of workers in these areas and more partnerships with academia are needed to address the problem, say industry officials and a representative of academia at a recent meeting.

John Balchunas, the workforce director for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) told a meeting of the International Society for Pharmaceutical Engineering on 2

June that 20,000 new workers will be needed in the next five to 10 years in gene and cell therapies and continuous manufacturing.

He added that “broad collaborations” between industry and universities can help bring new talent into the field.

Lindsey Silva of Genentech Inc. concurred that “we need the partnership between the industry and academia to make sure that we procure the talent that we need in the field.”

WFOTF Initiative Launched

A group within ISPE called the Global Pharmaceutical Manufacturing Leadership Forum (GPMLF) has committed its members to help bridge this skills gap through the Workforce of the Future (WFOTF) initiative.

At the virtual ISPE biomanufacturing meeting, representatives of Novartis AG and Genentech and a professor at the University of Maryland Baltimore County discussed their involvement in teaching and mentoring students in combination products, quality by design and quality risk management. These classes generally supplement the existing curriculum in computer science, biology and engineering. Also, a member of the forum discussed a recent program at North Carolina State University on gene therapy manufacturing.

What Keeps Executives Up At Night

The shortage of talent in the gene therapy field was cited as a concern by an official in the biotechnology field. Michael Paglia, senior VP of CMC operations for Elevate Bio, said his main constriction point in manufacturing gene therapy products has to do with “staff and talent and supply chain and the cost of goods and quality and access to capacity.” (Also see “Top US FDA Official Says New ‘Playbook’ Needed For CMC Reviews Of Gene Therapy Products” - Pink Sheet, 18 Jun, 2020.)

It is also this shortage that keeps pharmaceutical executives up at night, reports Antonio Moreira, a professor at the University of Maryland Baltimore County, who launched the workforce development efforts of the GPMLF. He described the work and the origins of the WFOTF in a 19 June interview with the Pink Sheet.

Moreira said the GPLMF is a group of around 60 quality and regulatory executives that meets twice a year, once in Europe and once in the US, usually a day before ISPE’s annual meeting.

These 18 companies are in the group: AstraZeneca PLC, MedImmune LLC, Mylan NV, Novartis, Pfizer Inc., Merck & Co. Inc., AbbVie Inc., Bayer AG, Novo Nordisk AS, Johnson & Johnson Innovation - JJDC Inc., Genentech Inc., Eli Lilly & Co., Bayer AG, Sanofi, Amgen Inc., Bristol-Myers Squibb Co., GSK Consumer Healthcare and Boehringer Ingelheim International GmbH.

About two and half years ago, they started to discuss workforce issues and “what keeps them awake at night,” Moreira said.

One of their major worries was not finding qualified workers: “They invest all this money in new facilities but cannot find qualified workers to staff them.”

He said that the employees they hire may be “great scientists or great engineers,” but have limited manufacturing experience.

The group started to discuss how to make the universities understand and “adjust the academics” to add in course work at the university level more tailored to the manufacturing sciences.

A friend of Moreira's who works at AstraZeneca suggested that he may want to get involved in this effort, as Moreira used to work at Merck before switching to academia.

To respond to this need, Moreira launched the workforce of the future initiative last year. There are about 20 people from the GPMLP involved in this effort from member companies. The group has forged partnerships at UMBC and at the University of California Davis.

Combination Products

Manfred Maeder of Novartis in Switzerland explained what led to the company's decision to launch a program on combination products at UMBC, where he flies into Baltimore to teach classes. Maeder said that of the top 20 innovative medicines products in 2019, over 30% of the sales came from combination products, and that "significant market growth is expected as US submissions continue to increase."

There are also instructors from Abbott Laboratories Inc., AstraZeneca, Biogen Inc., Johnson and Johnson and West Pharmaceutical Services Inc., as well as the US Food and Drug Administration.

For Novartis, "there is a need for combination products. In 2019 one-third of all products were from combination products." He said that the skills that are needed to fill these jobs are device experts, device transfer engineers, device human factors experts, plastics engineering experts, and industrial design experts.

What's more, he said that "these skills are not taught at university."

The courses include lifecycle management of combination products, risk management, and the regulatory process for combination products in the EU and US. Classes started in the fall of 2019 and are planned again in the fall.

QbD Lunch And Learn At UC Davis

Genentech's Lindsey Silva discussed the WFOTF effort she leads at UC Davis. The program emerged from the need to fill jobs in the next five to 10 years for employees with skills in biotech processes, development scientists, combination products and technology platforms.

Silva teaches a class on quality by design principles, an expert from Bayer teaches a class on quality risk management and another expert from Johnson and Johnson teaches a class on data management.

The classes, which were taught in the spring, are being incorporated into the computer science, biology and engineering curricula.

Silva said that "we were very fortunate to have great participation from the UC Davis faculty as well as industry leaders from Bayer and from Johnson and Johnson."

The class she teaches addresses "what does QbD mean and how has it evolved over time? How we do we identify a CQA [critical quality attribute] and what is not a CQA? And how does this go into process understanding so that when you go into commercial setting you have an understanding of how to conduct your validation."

Free Lunch For College Students

One of the best ideas they had was to sponsor a "QbD lunch and learn" in March.

"Who doesn't love free food when you are a college student? For the industry panelists we had people from Genentech, and industry panelists from AstraZeneca and Takeda."

The Benefits Of FDA Involvement

UMBC also offers a master's degree in professional studies in biotechnology. The class covers all the regulatory approval steps for a biotech product. The student develops an understanding of the process of biotech product development, including clinical stage, the design of clinical trials, and various regulatory submissions.

The course also addresses biosimilar compatibility, project team interactions, GMP manufacturing and compliance, vaccine regulations, and cell and gene therapies. This coursework also prepares students to meet with the FDA for "mock" pre-IND meetings. Students must prepare for an IND meeting with FDA and they must prepare for real world situations, and they must justify the use of a therapy to treat a particular disease, and must be prepared to defend their INDs.

Teaching the course are instructors from AstraZeneca, Autolous, Genentech, MacroGenics Inc. and the FDA.

Moreira reports that the class on mock IND meetings was a success. "We actually had three FDA people there asking questions. It was a great experience for students."

NIST Launches Program in Gene Vector Manufacturing

To address the need for workers in the gene therapy field, NIIMBL has also launched the world's first "hands on course" in gene therapy vector manufacturing at North Carolina State University in Raleigh, NC, said Balchunas.

Balchunas said that "we have run it at three sites in 2019, they all sold out very quickly. There is a lot of interest and a lot of demand for that course." The program is taught at NC State's Biomanufacturing Training and Education Center and supported by a NIIMBL grant.

Diverse Supply Of Talent Needed

Balchunas told the meeting that now is the time to take action to address worker shortages in the biopharmaceutical industry.

He cites a recent Deloitte report showing that biologics will comprise more than a quarter of the pharmaceuticals market by 2020. Further, the US FDA expects to review and approve between 10 and 20 cell and gene therapies each year by 2025. In North Carolina, he said that biopharma manufacturing jobs are projected to increase more than 15% in five years, and that a "significant number" of these jobs are in cell and gene therapy, and that COVID-19 will exacerbate the need for workers trained in these industries.

He said that the biopharmaceutical industry is going to need an increasingly diverse supply of talent at all education levels to meet the skills gap.

There also has to be an effort to turn around the mindset of how students view biopharmaceuticals jobs.

"It is critical to get more youth and college students interested in biopharmaceutical careers. Yet this is challenging because students view these as operator jobs and not being sexy, and they equate biopharmaceuticals with a white lab coat."

