BIOMANUFACTURING

BIOMANUFACTURING 2020
A LOOK AHEAD

Part of Proventa International's EU Biomanufacturing Strategy Meeting 2019
Radisson Blu Zurich Airport, Switzerland - October 8, 2019

Attendee Statistics - Who Went and What They're Investing In

Highlights from All Our Tracks This Year

The Top Strategic Challenges for Biomanufacturing, 2020 and Beyond

An Expert Look at the Next Five Years in Biomanufacturing

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Introduction

Proventa's Biomanufacturing Meeting has just concluded for another year, showcasing the success of the company's innovative format: delegates and sponsors alike were pleased and surprised by the usefulness of Proventa's unique roundtable discussion format, the amount of connections made with peers and the seniority and experience of attendees present.

Discussions hit on the biggest topics of the moment, from how big data and machine learning can be integrated into QbD, to the advantages of real-time sensor technologies for automated monitoring and control of upstream/downstream bioprocesses.

The Future of Biomanufacturing

This report features a wealth of information for those who attended the 2019 strategy meeting and indeed those who did not, but more importantly looks beyond the event to the future: it contains not only statistics showing job titles and investments of this year's delegates, but highlights from the event talks themselves and our facilitators' impressions of how biomanufacturing will evolve and change over the next five years.

There is a wealth and variety of information packed into the pages of this report: we hope you find them of interest and use, and enjoy your time reading.

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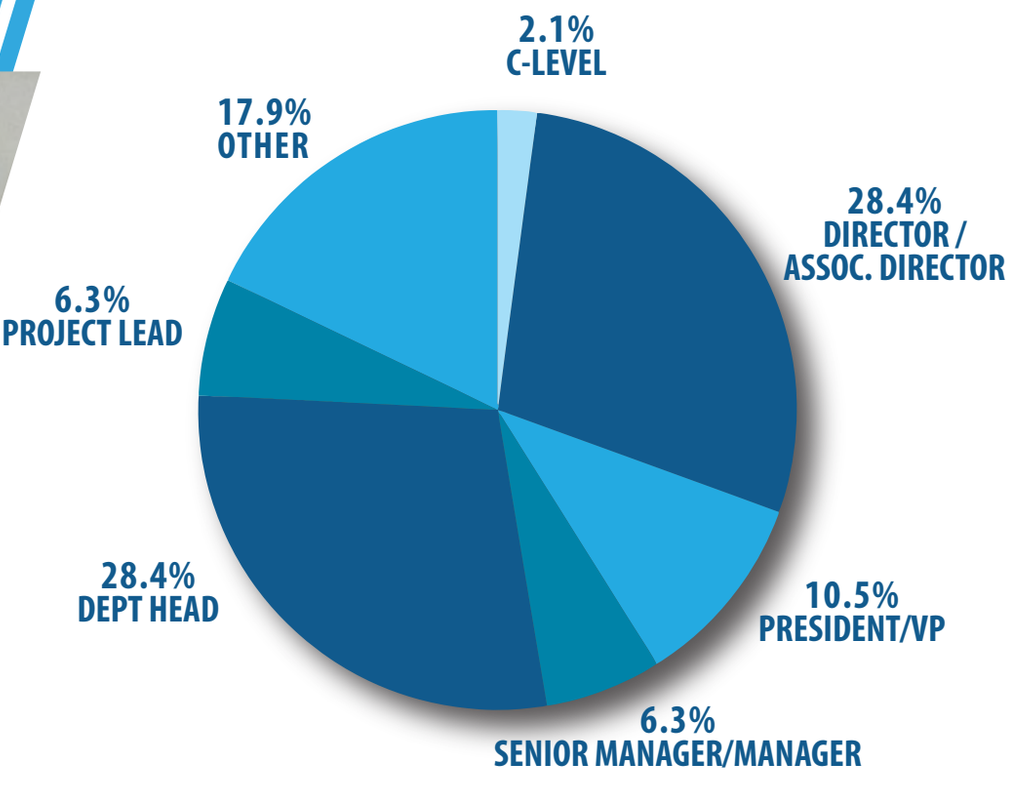

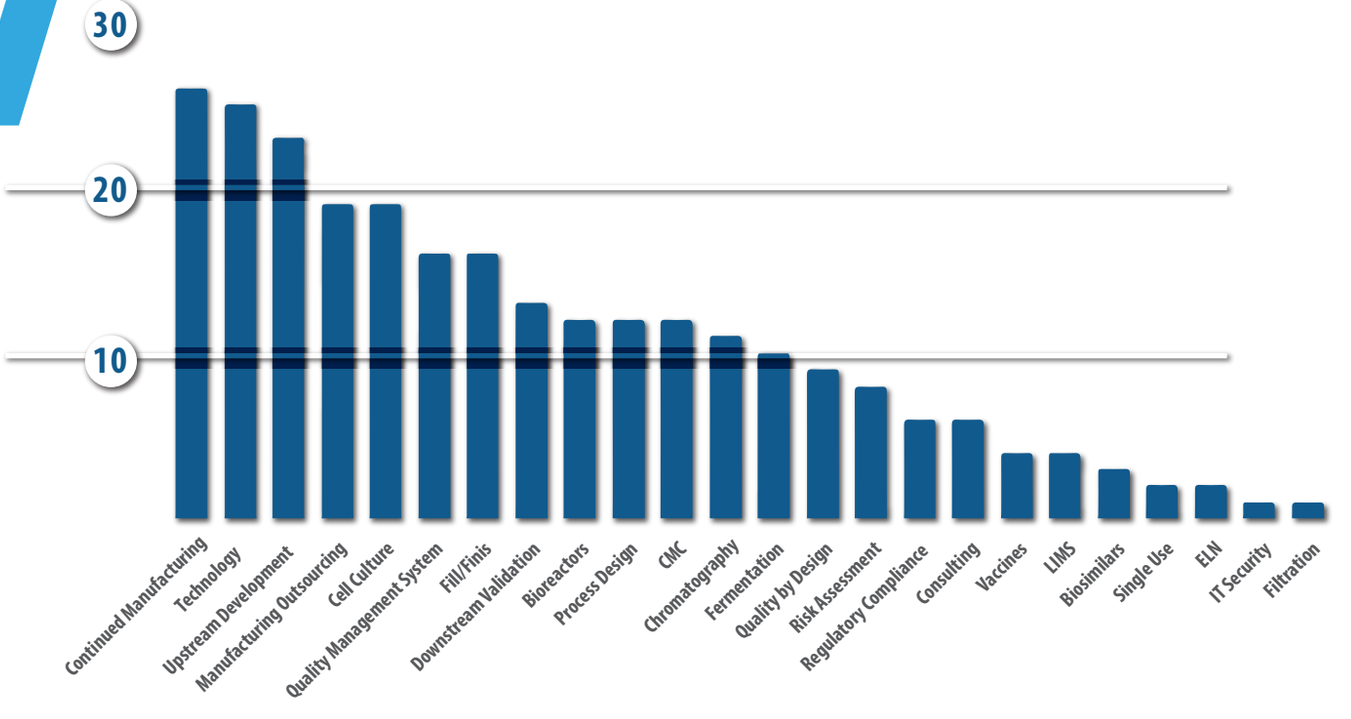

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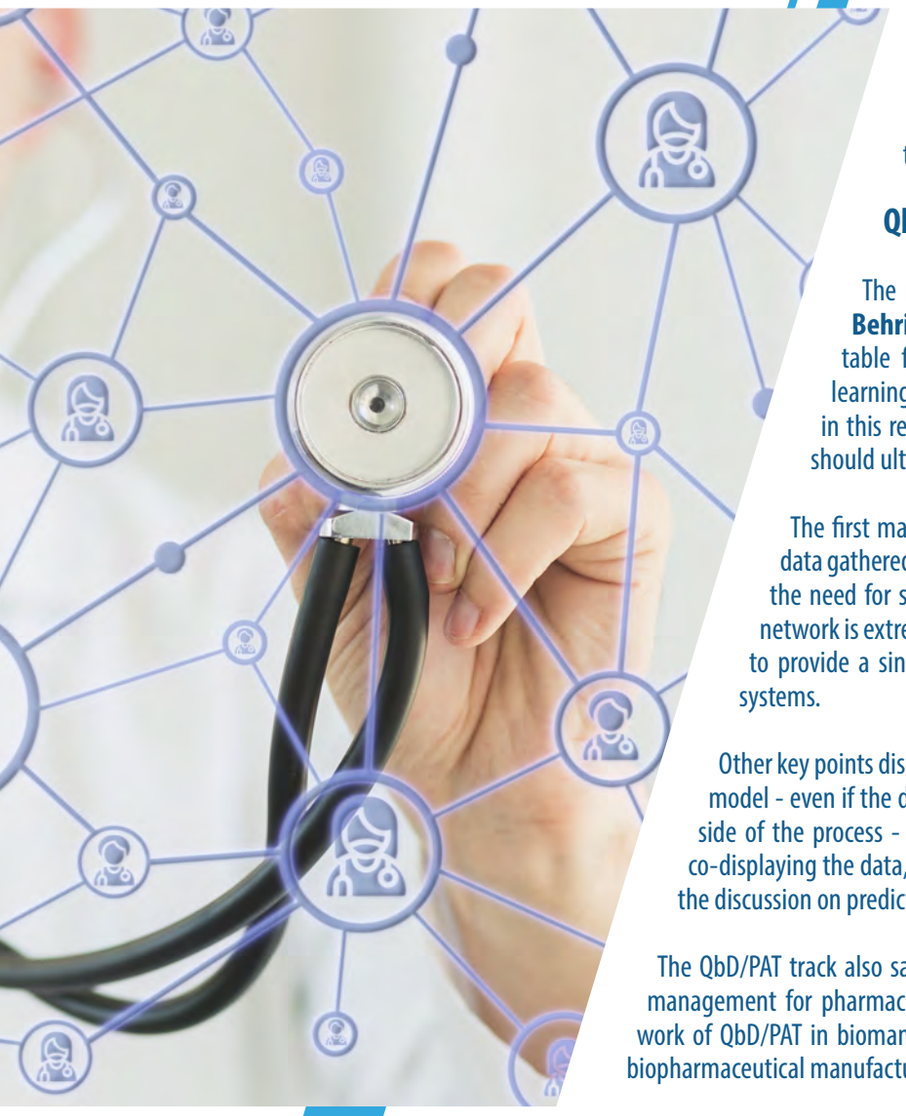

The 2019 **Biomanufacturing Strategy Meeting** saw engaging roundtables across four main tracks, with everyone who attended finding something of use. The tracks were: upstream/downstream; continuous manufacturing; QMS; and QbD/PAT.

QbD

The morning's QbD session, directed by **Max Corbett of CSL Behring**, was a very strong start to an important track. The roundtable focused specifically on integrating big data and machine learning, and aimed to discuss in depth where the industry should go in this regard, how to harvest and process data, and how such data should ultimately be used.

The first major point discussed was around data ownership: who owns data gathered, and who's responsibility should it be? Delegates brought up the need for systems fit to store and spread knowledge, and that a data network is extremely important, especially in the early stages of the process, to provide a single source of truth that can enable good interfacing of IT systems.

Other key points discussed were the need to bring all R&D data together into one model - even if the data itself is limited compared to data on the manufacturing side of the process - as there is a great deal of value contained even in simply co-displaying the data, as well as talking about the need for a focus group to move the discussion on predict and control process models forward.

The QbD/PAT track also saw roundtables on enabling integrated knowledge and risk management for pharmaceutical process development under a QbD framework; the work of QbD/PAT in biomanufacturing automation; and a look at QbD/PAT applied for biopharmaceutical manufacturing.

2019 Event Highlights

Continuous Manufacturing

Continuous manufacturing (CM) was another key track this year, featuring roundtables on continuous processing as the solution of the future, on manufacturing strategy and CM, and the latest CM advances and approaches that could benefit professionals in the area.

QMS

On the QMS track, Inka Bosse of MSD looked at keeping abreast of QMS and cGxP amid increasing dynamism, while Dr. Ramzan Tabasum of CSL Behring discussed how QMS could work in a fully automated paperless facility. The track ended with an engaging and enjoyable discussion from Poul Henning Poulsen, Corporate Vice President, Strategic Quality Development at Novo Nordisk, on simplifying the QMS to secure a better level of compliance. This session was a light-hearted discussion about the need to remove overprocessing from biomanufacturing as a whole.

In this roundtable, delegates from several leading pharmaceutical giants discussed the ongoing push towards "no compromise on quality" - and ironically how this constant drive has meant the creation of an overwhelming burden of processes and checks which could itself damage quality output.

Poulsen described his own attempts to combat this process creep, first cutting out every single step that clearly wasn't needed before focusing on the remaining steps one by one. His maxim was that in order to simplify, one must standardise before cutting processes to the bone, refining until only the absolutely essential steps - as required by law - were in place. In the course of this, he stated that the time of more than 200 full-time employees had been saved.

The consensus reached in the roundtable was that too many details were harming the productivity and efficiency of the sector. It was thought that instead of a list of rules stating what should not be done, only what should be done should be mentioned.

The conversation then moved on to pushback from authorities, with delegates agreeing that individual inspectors do not necessarily represent authorities, and that explaining certain decisions and cut-backs, and pushing back against reactionary judgments, should allow for greater slimlining of processes without compromising on quality.

The session ended with a discussion around working with only trusted suppliers to ensure quality and compliance, with controlled e-learning sometimes necessary to ensure supplies and staff are informed of relevant requirements.

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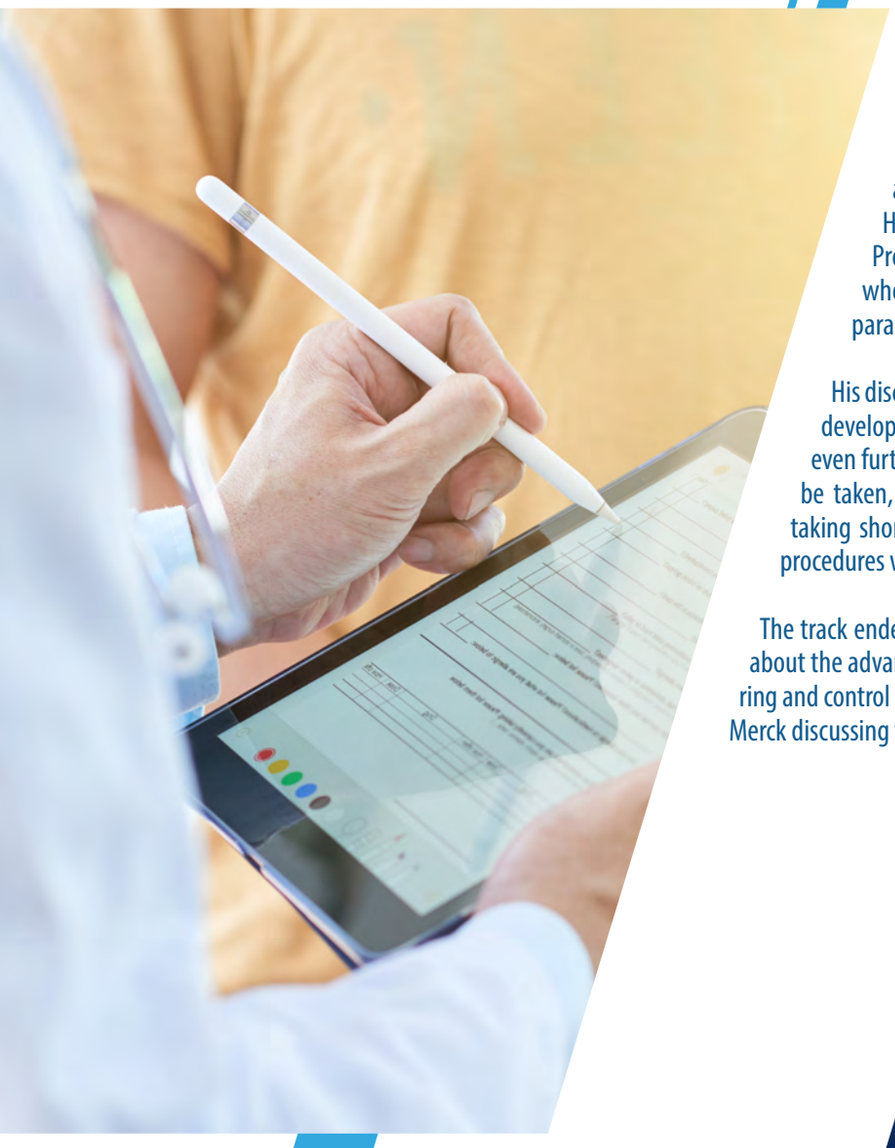
2019 Event Highlights



Upstream/downstream

The last track of the day, upstream/downstream, began with Torsten Wagner of Merz Pharma discussing the impact on industry of utilising single-use tech on a commercial scale, as it related to costs, obstacles and expectations versus reality. He was followed by Kristoffer Rudenholm Hansson, Senior Vice President of Technical Operations at BioInvent International AB, who gave an excellent roundtable on process development in parallel with cell line development for antibody production.

His discussion centred around how best to utilise the time for cell line development, and whether it was possible to speed up the process even further. In addition, he talked about possible shortcuts that could be taken, and discussed the need to frontload some activities when taking shortcuts, costing further money but ensuring the right quality procedures were there at the start of proceedings.

The track ended with two more talks, with Giovanni Campolongo speaking about the advantages of real-time sensor technology for automated monitoring and control of upstream/downstream processes, and Pascal Torregrossa of Merck discussing the adding of SU systems into existing commercial production.

Key Delegate Challenges 2020 and Beyond

One of the most important resources available to any senior figure in biotech or pharmaceuticals is an understanding not only of the field at present but where the field is going, and the key obstacles that any company in the sector faces.

Proventa International surveyed a number of major players in the field prior to our 2019 event, using expert opinion and insider knowledge to uncover out of the many obstacles on the horizon the major challenges to overcome in the next few years.

Major Challenges - 2020 and Beyond

New technology - integration and strategy

The standout winner in Proventa's survey of needs was, unsurprisingly, focused on new technology and IT capabilities. The foremost keywords on everybody's lips, the coming few years will see radical changes in fundamental pharmaceutical processes around increasing digitalisation, automation and integration, with many processes and key datasets moved online or into the Cloud.

Streamlining and process optimisation

Following on from the first point, the continuing challenge of optimising old processes and reducing inefficiencies continues to be a major challenge in the biomanufacturing industry, with the move online trying many companies' resources.

Technology transfer

Tech transfer was another highly-rated challenge for biomanufacturing experts: the move from one facility or process train to another creating widespread headaches within the industry.

Recruiting and training

Recruiting and training remains a perpetual challenge within the industry, with headhunting and hiring specific skill-sets also mentioned as a major challenge for pharma experts.

Compliance and regulatory

Keeping up with a fluctuating regulatory framework and ensuring compliance across a range of processes is a key challenge in biomanufacturing, with NDA-filing and fears of Brexit also mentioned among the major regulatory worries.

Key Delegate Challenges 2020 and Beyond

Manufacturing

After those key issues came a number of more specific manufacturing industry issues, ranging widely from manufacturability to control-critical steps in the manufacturing process to continuous manufacturing, which was cited several times as of importance to key industry players.

Process design and control

Process modelling, validation and design, as well as process analytical technologies, were all mentioned as a possible challenge in the coming years.

Meeting timelines and budget

Another of the top challenges mentioned involved various timeline and budget concerns - with challenges mentioned including cycle time reduction, validation timelines and staying on budget.

Facility startup and new lab installation

Facility startup and new lab installation were both referenced as key challenges in the years ahead, linking with technology transfer to suggest such organisational problems are high on many companies' lists.

Management and selection of CMOs

Finally in the top ten key challenges faced by pharmaceutical experts, the management and selection of contract manufacturing organisations was listed as a challenge by several key players in the industry.

A Look Ahead:

Expert Opinion on the Future of Biomanufacturing

The Future of Biomanufacturing

In contrast to many of the forecasts regularly demonstrated in areas across the pharma sector, statistics for the future of biologics and biomanufacturing seem strong. In the decade to 2020 the market share for biosimilars will be equal to new molecular entities (NMEs) at 50% each, up from biologics cornering only 5% of the market at the start of the decade. In terms of pipeline, during the 2010s biologics surpassed NMEs in numbers for the first time, with 60% of all pipeline drugs expected to be biologics by 2020.

As biologics development has increased so steadily, the push for new technological developments has greatly increased, focused on higher yields and lower costs. These needs have seen the rise of several innovative models and technologies which are only now finding their feet: arguably the most notable of these being the take-up of single-use technologies and modular equipment, used in all stages to cut costs and remove the potential for contamination.

Other new models and processes which could have a major impact on biomanufacturing in the next five years include perfusion technology, in silico modelling and of course the ever-present topic of automation and digitalisation. To find out more about what the future holds, we spoke to some of our expert facilitators on site for their opinion.

Wide Scope for Progress

When surveyed, many of the experts at the 2019 Biomanufacturing event expressed their view that no one particular field stood out as being of greater importance than the others present, particularly in terms of having a greater impact on the future of the field. One facilitator suggested that there was something to learn in every track on the agenda, with possibly only product manufacturing unaccounted for as a topic which could be of importance in the near future.

A Look Ahead:

Expert Opinion on the Future of Biomanufacturing

QbD

The above expert did, however, suggest that QbD will certainly continue to be of great importance in the coming few years. This idea was echoed by several of our facilitators, including a Director of Drug Product and Biologics at a leading pharma company, who suggested that QbD, PAT and GMP will all have a big impact in the near future, and are important to know more about. She added that discussion around ICH guidelines will also be of importance to experts, as there is currently still confusion on how to implement these, and many experts are yet to understand the full picture around this legislation.

Single-Use Equipment

She also suggested that in her opinion, single-use equipment had already been intensely discussed by area experts, and that while important for the future was by now understood and perhaps even overstated. This idea was refuted by some other attendees, including a Head of Manufacturing Quality, who suggested that many companies are now moving into this area and that it will play a huge part in biomanufacturing in the near future.

Digitalisation

One facilitator noted that an even bigger change than single-use equipment will be digitalisation, and with it increased automation in the workplace, particularly moving from paper records and unstructured data to computerised storage and filing. He said that in this case one of the topics that will continue to be of huge import in the next five years is data integrity itself - the requirements and tools for digitalisation, maintaining system validations and understanding how to work with the new systems put in place to this end.

Regulatory Issues

Another facilitator cited regulatory issues as those of most interest to him in the coming months. He thought that a change that would greatly improve the work of biomanufacturing professionals would be a standardised regulatory approach in a number of areas, where currently many different rules exist in different countries, creating excessive waste and great cost to pharma and biotech companies.

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