



BIOMANUFACTURING TECHNOLOGY ROADMAP

EXECUTIVE SUMMARY

Acknowledgments

The following member company participants are acknowledged for their efforts and contributions in the production of this roadmap document. (Overview section authors highlighted by*.)

Abbvie

Derek Sawyer
Li Malmberg
Natarajan Ramasubramanyan

Asahi Kasei Bioprocess

Kimo Sanderson

AstraZeneca

Rick Lu*

Bayer

Edgar Sur
Ingmar Dorn
Janet Wendorf
Joerg Heidrich
Thomas Daszkowski

Biogen

Eliana Clark*
Phil McDuff

CRB

Kim Nelson

Emerson

Robert Lenich

Fujifilm Diosynth Biotechnologies

Stewart McNaull*

GE Healthcare Life Sciences

Jonas Astrom

G-CON

Maik Jornitz

GSK

Charles Heffernan*
David Paoletta
(formerly) Louise Duffy

ImmunoGen, Inc.

Sandra Poole
Thomas Ryll*

Janssen

Patrick Sheehy
(formerly) Ranjit Thakur*
Stefan Merkle*
Timo Simmen

Kaiser Optical Systems

David Strachan

Lonza

Rajesh Beri*

M+W Group

David Estapé

Merck KGaA,

Darmstadt, Germany
Jonathan Souquet*

Merck & Co., Inc., Kenilworth, NJ, USA.

David Pollard
Wayne Froland
(formerly) Beth Junker*

Millipore Sigma

David Beattie

NNE

Morten Munk

Novasep

Jean-Luc Beulay

Pall

Hélène Pora

Pfizer

Joris Smets*
Paul McCormac*
Will Waterfield

PM Group

Andy Rayner

Roche

Oliver Stauch*
Paul Bezy
(formerly) Tina Larson*

Sanofi

Beate Mueller-Tiemann
Thomas Sauer

Sartorius Stedim

Lars Boettcher

Shire

(formerly) Alan Glazer
(formerly) Bert Frohlich*
Chun Zhang
(formerly) Joerg Ahlgrimm

Takeda

Palani Palaniappan

Thermo Fisher Scientific

Craig Smith

UCB

John O'Hara

BioPhorum

Operations Group

Steve Jones*
Paul Ilott*
Linda Wilson*
Bob Brooks
Clare Simpson*
Jonathan Dakin
Justin John

Publication Team

Les Pickford
Karen Kilbride
Steve Pitt

The steering committee would like to thank the following non-member participants for their contribution to the roadmap meetings:

Alexion

Al Boyle

Biopharm Services

Alan Calleja*
Andrew Sinclair

Eli Lilly

Todd Winge

Novavax

Tim Hahn

A*STAR (Agency for Science, Technology & Research)

Andre Choo
May Win Naing

AMBIC, John Hopkins University

Michael Betenbaugh

BioProNet

Alan Dickson

BPTC

Tom Ransohoff
Gary Gilleskie

Centre for Process Innovation (CPI)

Richard Alldread

ETH Zurich

Massimo Morbidelli

MIT

Charles Cooney
Chris Love

NIST

Michael Tarlov

UCL

Dan Bracewell

University of Delaware, NIIMBL

Kelvin Lee

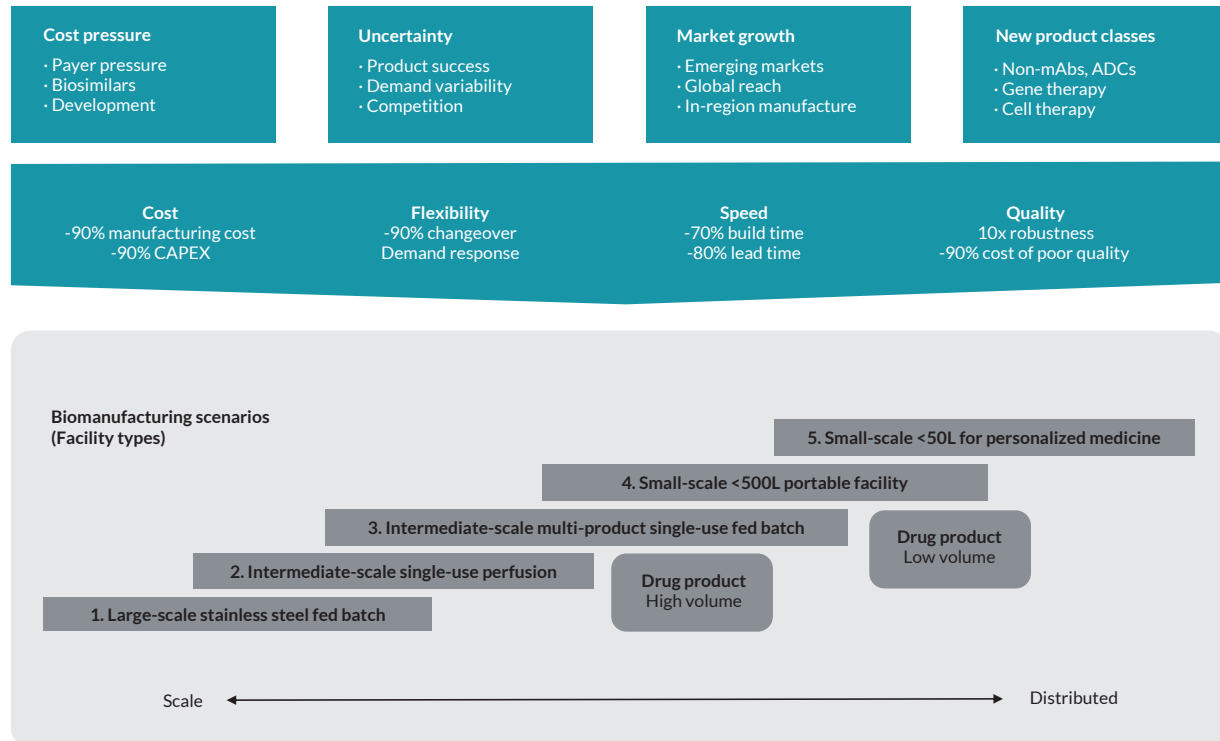
Contents

Current trends	4
Conclusions and recommendations	8
 Process Technologies	9
 Automated Facility	10
 Modular and Mobile	11
 In-line Monitoring and Real-time Release	12
 Knowledge Management	13
 Supply Partnership Management	14
Overarching next steps	15
Appendices	18

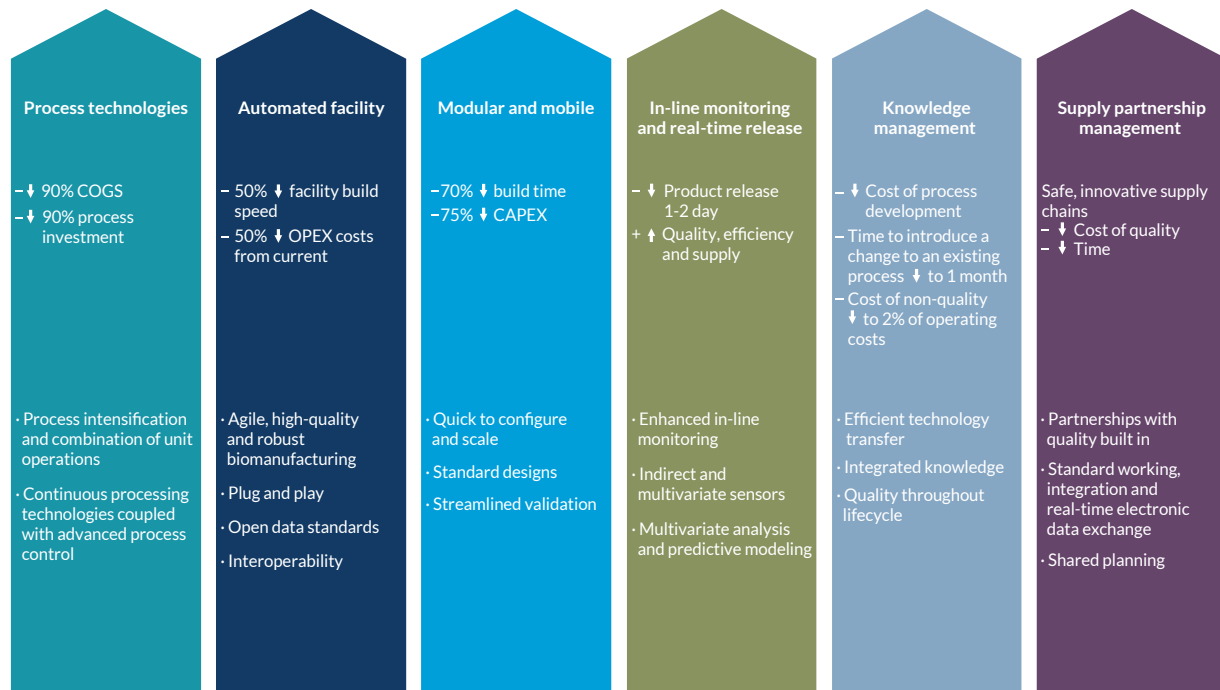
Current trends in the biopharmaceutical industry – including continued market growth, the arrival of new product groups, cost pressures and the trend towards localized manufacturing – are exerting unprecedented pressure on biomanufacturers to innovate biomanufacturing platforms. To accelerate the industry's journey, a technology roadmapping process has been established to determine common biomanufacturer needs and to share them openly with supply partners, academics, regulators and government agencies so that directions can be aligned and collaboration enabled.

Thirty-one member companies contributed to this first edition, with additional input from academics, supply partners and agencies. Over 160 people are now actively involved in the roadmapping process. We see the first edition as an initial step, setting a broad vision for the future of biomanufacturing that will catalyze industry action. We welcome and look forward to your input and know that by working together we can make this vision a reality.

Figure 1: Roadmap vision



Enabling technologies and capabilities



ADCs – antibody drug conjugates, mAb – monoclonal antibodies, COGS – cost of goods, CAPEX – capital expenditure, OPEX – operational expenditure

Market trends are exerting unprecedented pressure on the biopharmaceutical industry to change:

1. **Market growth** – rapid growth continues, diversifying into new geographies and innovative therapies
2. **New product classes** – the arrival of non-mAb products ADCs, gene therapy and cell therapy
3. **Uncertainty in product success and sales** – global distributed markets are adding more uncertainty to the existing clinical, regulatory and demand risks
4. **Cost pressure** – payer pressure, the arrival of biosimilars and access to developing markets will continue to drive down manufacturing costs and the capital available for investment.

As a result, step changes in business driver performance are required in biomanufacturing:

1. **Quality** – 10x transformation in manufacturing robustness and reliability to improve product quality and reduce the waste associated with non-quality
2. **Cost** – 90% reduction in the cost to manufacture and capital expenditure
3. **Flexibility** – improve the response to variability in demand and new products. Reduce the product changeover time by 90%
4. **Speed** – reduce new facility build times by 70% to scale globally. Compress the production lead times by 80% and product release times to less than one day.

In response, manufacturing facilities will not remain ‘one size fits all’.

New, intermediate-scale facilities have already started to emerge and will further expand and develop. As personalized medicines become a reality, widely distributed portable facilities will also emerge, completing a full range of biomanufacturing scenarios as identified through the work of this collaboration and described in the general categories below:

Drug substance







- 1. Large-scale stainless steel fed-batch**
 - low cost at high utilizations, high capital and long build times
- 2. Intermediate-scale single-use perfusion**
 - medium throughput production of a broad variety of proteins, more easily reconfigured or ‘scaled across’
- 3. Intermediate-scale multiproduct single-use fed-batch**
 - medium to low throughput production of a very broad variety of proteins, more easily reconfigured or ‘scaled across’
- 4. Small scale <500L portable facility**
 - low throughput production units, can also be rapidly ‘scaled across’ and deployed into multiple regional markets
- 5. Small-scale <50L for personalized medicines**
 - very low throughput, patient-specific preparation. Many production units, globally distributed.

Drug product

- 1. High-volume facility**
 - large automated product flow lines. Low manufacturing cost at high throughput rates with long build times, high capital costs and relative inflexibility
- 2. Low-volume facility**
 - small standardized robotic filler. Modular design to enable rapid ‘scale across’, fast product changeover and lower capital costs. Readily combined with intermediate-scale drug substance manufacturing.

To deliver the future biomanufacturing scenarios and the required performance, the industry must deliver step changes in six enabling technologies and capability areas.

Figure 2: Enabling technologies and capabilities vision and benefits diagram

Enabling technologies and capabilities	Vision		Benefits
Process Technology	Process intensification – intensifying production through highly concentrated reactants and products, and combining unit operations into single units		<ul style="list-style-type: none"> • Minimalized capital investment • Streamlined validation processes • Decreased total cost of goods
	Continuous processing – new separation and media technologies, coupled with advanced automation and process control		<ul style="list-style-type: none"> • Flexibility for smaller patient populations • Speed • Reduced cost and reduced facility size
Fully Automated Facility	'Plug and play' for fast response to capacity demands, with minimal staff, time to changeover and regulatory observations that delivers products of lowest cost and highest quality, from receipt of raw materials to final drug product		<ul style="list-style-type: none"> • Quicker and cheaper facility builds and lower lifecycle costs • Readily available and usable data • Reduced manufacturing deviations and non-conformances • Streamlined real-time release • OPEX reduction
Modular and Mobile	Manufacturing systems that are quick to configure, assemble, scale and relocate, using 'plug and play' standard designs and standard validation approaches		<ul style="list-style-type: none"> • Speed to clinic and market • Rapid tailoring of capacity to meet demand • Manufacturing process available in weeks • Mobility and repurposability of facilities throughout lifecycle • Reduction in CAPEX
In-line Monitoring and Real-time Release	Enhanced in-line monitoring unlocks potential for robust material characterization, process control and assurance of product quality		<ul style="list-style-type: none"> • Enabler of real-time release, product released in 1–2 days • Improved product quality, operational efficiency and Reliable Supply
	Hardware for advanced in-line monitoring devices, including indirect and multi-attribute sensors		
	Software to enable multivariate analysis, predictive models and closed feedback control loops		
Knowledge Management	Integrated knowledge of product and process technology across the development, manufacturing and commercial value streams		<ul style="list-style-type: none"> • Accessible and applicable biomanufacturing information and knowledge, driving down development costs • Efficiency and quality throughout product lifecycle
Supply Partnership Management	Supply Partnership Management undertaken in a spirit of openness and trust to drive successful collaboration, making best use of technology and integration of systems and processes		<ul style="list-style-type: none"> • Lower cost/quality ratio for raw materials, services and CAPEX investment • Faster to develop, produce and make changes • Safe, innovative supply chains

CAPEX – capital expenditure, OPEX – operational expenditure

Conclusions and recommendations

The conclusions and recommendations for each of the six enabling technology and capability areas, followed by the overarching next steps for the roadmap, are captured in this section.

Process Technologies

Conclusions

The choice of which process technologies to pursue will depend heavily on the desired outcomes and specific situation of a given company. A company trying to significantly reduce the cost of goods for a single product will likely require different technology improvements to a company looking for increased flexibility in the manufacture of a multiproduct portfolio. Before pursuing any given technology, companies should consider what intensification strategy makes the most sense for its set of circumstances. Several additional factors should be taken into consideration, including existing manufacturing capacity, prior knowledge with existing technologies, size of company and portfolio, potential market for the product and the stage of product lifecycle. The impact of a technology can then be weighed against the risk of successful implementation. In almost all cases, it is clear that collaboration across multiple organizations will be required to bring such innovations into routine use.

No single technology will be right for every company. However, a focused development effort on a select few could have a significant and broad impact in our industry. These include:

1. process intensification to increase titers and reduce volumes; reducing the number of unit operations and creating more streamlined ways of working
2. richer, chemically defined medias, feeds and supplements that enable higher cell densities, higher titers, simplified media make-up and longer media stability
3. robust, scalable harvest technologies and cell retention devices that minimize large capital investments and can handle ever-increasing cell densities
4. standardized modular claims for robust viral clearance approaches that provide streamlined regulatory processes and ease process development
5. constraints and space requirements for buffer preparation
6. single-use technologies to increase flexibility and improve closed systems, resulting in a decreased capital cost and a decreased total cost of goods over the lifetime of a product.

Recommendations

Most of the technologies identified in this roadmap will have an incremental impact on the cost of goods and operational flexibility but are still important in an increasingly competitive landscape. Looking further into the future, disruptive technologies capable of revolutionizing biomanufacturing will also be considered:

- industry consortiums can address the biggest challenges, such as Chinese hamster ovarian cell productivity and specificity, and viral clearance but these efforts would benefit from support by both academia and vendors. Development of these future disruptive technologies carries an increased risk of success, but the potential for higher reward
- implementation of continuous processing significantly reduces the size and cost of a facility required to produce a given amount of product, which translates into reduced fixed costs and hence a reduced cost of goods.

The advances described in this roadmap will provide a meaningful level of benefit over current practices that will reduce manufacturing costs and enhance patient access over the 10-year horizon considered by the authors. This would be a first step in reducing the manufacturing cost of biopharmaceuticals towards that of small molecule drugs. Further pronounced benefits become possible with the addition of disruptive technologies that will require a longer time horizon and broader collaborations among industry, suppliers, regulators and research communities for development and commercialization.

Automated Facility

Conclusions

It is becoming obvious that with the advent of autonomous systems the communications between equipment from different suppliers will not be a 'nice to have' but will become mandatory. In addition, because these systems will span so many different areas of specialty it is incumbent that collaborations between end-users, engineering companies, skid suppliers, regulators and equipment vendors will be the catalyst for change across the biopharmaceutical industry.

Over the next 10 years, there will be a rapid change in both the bioprocessing technology and automation technology employed in facilities. Adapting to change and a willingness to collaborate will be the hallmarks of the leading companies, both end-user and supplier. While some may see this as a battle to determine winners and losers regarding the automation providers, this type of focus will only serve to delay change and lead to the adoption of less technology in the near term as companies wait to see what evolves. By working together collaboratively to solve common problems and enabling the speedy adoption of new technologies, we will realize the key goal of bringing new medicines to markets faster. The summary of conclusions from this report are:

1. full integration is the key enabler that allows quicker and cheaper build times. Open standards and open system design principles enable quick and easy configuration
2. management of data is a challenge as data volume grows. Extraction/visualization of information out of the data is an imperative for effective and efficient biomanufacturing
3. high availability depends on the automation of IT systems and databases. Work with supply partners is critical in this space and is dependent on technology development for failure detection and swap-over
4. reduction of manual labor through the use of robotic systems and mechanization will reduce the high labor costs of biopharmaceutical facilities and improve process robustness
5. new and converging technologies offer the elimination of errors through paperless operation and guidance of maintenance and support activities, a reduction in cost through the use of smart scheduling techniques to maximize utilization, and the move to cloud and virtualized technologies.

Recommendations

The Automated Facility report offers the following recommendations:

1. evolve collaboration for open interoperability standards from 'talking' to 'doing' through joint projects with end-users, suppliers and regulatory entities
2. benchmark automation best practices in other industries for potential solutions for the biopharmaceutical industry, such as in the finance, semiconductors and automotive industries
3. collaborate with standards organizations, especially those focusing on open systems, and form technical committees to develop standards
4. invite non-members (and those from other industries) to contribute and collaborate on projects that cut across industries.

Modular and Mobile

Conclusions

Modular and Mobile manufacturing techniques have the potential to address several key issues facing the industry, such as the large capital expenditures required well in advance of demand, high inventory levels, long cycle times, the high cost of goods and the lack of flexibility in modifying facilities or adopting new technologies. Modular and Mobile addresses these issues by enabling the rapid technology transfer and launch of new products, rapid tailoring of capacity with demand, repurposing of facilities to increase lifecycle, mobility of facilities to enable localized patient treatment or pandemic response, and miniaturization to enable personalized medicine.

Recommendations

To realize the benefits of Modular and Mobile, the industry will need to make progress with the following recommendations:

1. develop a standard, simple, fit for purpose design of facilities and processes packaged in a modular format. These modules can then be fabricated, tested and delivered more quickly and at a lower cost than traditional facilities. They can be added or removed as needed, without interrupting operations, and can be repurposed to align capacity with demand
2. standards will be required to define the capabilities and interconnections of the facility, room, process, equipment, automation and single-use systems with a key need to focus on interconnections. This will require collaboration between pharmaceutical companies and suppliers
3. collaboration with regulators will be required to enable a new regulatory strategy where the facility is treated as equipment for purposes of validation and qualification, allowing faster regulatory licensure of follow-on capacity additions or new products
4. operational robustness, operator safety, product quality and, ultimately, patient safety will be improved through standardization and continuous improvement
5. efficiencies in drug product operations and the supply chain inventory of drug substance will be improved through design and co-location of drug substance and drug product facilities.

Using these strategies, drug manufacturers can successfully respond to the market trends and business drivers in the industry enabling the faster introduction of new products to market, improving quality and improving the supply chain performance. These changes will help the industry to reduce cost, enable the development of new therapies and increase patient access to medicines.

In-line Monitoring and Real-time Release

Conclusions

Currently, the majority of testing required for process, environmental monitoring and testing of bulk drug substance or drug product is not performed in-line. Off-line analysis requires sample collection, labeling, transport to the quality control lab, sample receipt and logging, sample testing and the communication of results; the entire process is inefficient. A substantial number of tests are time consuming and require many days to complete, e.g. adventitious agent testing. Off-line analysis increases the product release time, which in turn increases the total inventory time and the total cost to supply.

Analysis has shown that 60–70% of tests are performed either at-line or off-line. The release testing of bulk drug substance (>15 tests) is performed off-line in quality control laboratories. Certain release tests are of a significant duration, e.g. seven days for bioburden, 35 days for virus testing. To achieve the 5–10-year goals (e.g. total cost to supply and time to release), significant investment is required for developing new in-line methods or converting off-line methods to rapid at-line methods.

Implementing in-line real-time monitoring for bioprocesses presents unique challenges given the complexity, variability of raw materials (particularly living organisms), the move from stainless steel to single-use equipment and the potential shift from batch to continuous processing. The key to successful implementation in a fully automated facility will rely on the availability of robust, reliable, low-cost and easy to maintain in-line probes. A commitment must be made very early in the product lifecycle to develop a process with in-line probe technologies.

Recommendations

Technologies are widely available for in-line measurement of pH, temperature, dissolved oxygen, viable cell density of high-viability cultures, conductivity, total organic carbon and metabolites (such as glucose and lactate). Promising technologies, e.g. Raman spectroscopy and near infrared spectroscopy, should continue through development for measuring product quantity, viability, etc. Raman and/or near infrared probes may drastically reduce the need for at-line and off-line testing of bioreactor samples.

New sensor technologies developed should be pre-calibrated, robust for the duration of use, stored in a dry state and used multiple times (for reusable equipment, biomanufacturing Scenarios 1 and 3) or integrated with the disposable system (Scenarios 2 and 4). Ideally, sensors should have the capability to monitor their performance and predict when they will fail, i.e. 'intelligent sensors'. There is also the need to consider redundancy and intelligent mechanisms that activate the redundant sensor automatically without an adverse impact. Consideration should also be given to the development of multi-attribute sensors that are capable of measuring more than one desired property simultaneously. There will be the need to balance between the combination of sensing parameters in one probe leading to poor analytical power compared to dedicated systems. The current state of sample analysis for process monitoring highlights the need for a significant investment in the development of new, or the modification of existing, technologies to achieve the goal of exclusively using in-line technologies for real-time monitoring of in-process and environmental testing samples.

The use of various measurement and control devices will require sophisticated automation solutions. The increased use of real-time, at-line testing will generate greater quantities of data that cannot be handled by today's operating systems. An integrated approach to real-time data management and multivariate data analysis programs will increasingly be required to meet the needs of the process. These multivariate data analysis programs will need to seamlessly integrate into the automation architecture of unit operations to deliver the full benefits.

Global regulatory alignment is critical for in-line monitoring and real-time release. Few companies will fully adopt this approach if regulatory agencies are not aligned globally. Therefore, it is important to not only develop the technologies of the future but to seek regulatory engagement and buy-in throughout the process. The desired state aligning across technology, process control and regulatory acceptance will enable global supply from advanced, commercialized manufacturing processes.

Knowledge Management

Conclusions

The key benefits from a strong knowledge management system are speed to market, cross-product learning and efficiency throughout the product lifecycle. Knowledge management significantly impacts on cost, speed and quality metrics through explicit as well as tacit knowledge collection/capture, dissemination/sharing and enrichment/reuse.

- **Cost** – the embedded use of knowledge management tools for product and process knowledge, and structured lessons learned, results in efficient manufacturing processes, fewer errors and a reduced cost of supply/development
- **Speed** – well structured and coordinated product/process information management (i.e. the ‘findability’ of information) can significantly impact on the time to release products and the time to introduce changes to an existing process
- **Quality** – improved management of multiple knowledge formats and easy access to information (i.e. its ‘findability’) increases the capability to understand how critical process parameters impact on critical quality attributes, improves control and reduces the occurrence of manufacturing out-of-specification product.

The impact on specific metrics of well structured and coordinated knowledge management approaches increases towards the 10-year time horizon, due to the substantial growth in knowledge generation as the business and technology opportunities identified in the roadmap are realized.

Recommendations

The Knowledge Management report recommendations are:

- the biopharmaceutical community (the industry and its stakeholders) can advance information technology (i.e. tools and systems) by articulating what knowledge and knowledge flow is, defining organizational knowledge flow challenges, developing best practices and biopharmaceutical use cases (based on the principles laid out in the report). These actions will create real-time, networked knowledge management systems throughout the biopharmaceutical industry
- knowledge leaders can identify incentives and motivations for individuals, within their own organizations, and influence the biopharmaceutical industry for strong knowledge management systems
- engage with academia for biomanufacturing workforce training and development with respect to evolving data to increasingly usable information.

Supplier Partnership Management

Conclusions

Supply Partnership Management is key to the successful implementation of the developments highlighted in this roadmap.

There is considerable scope for improvement in the degree of openness and trust. Doing so will enable the integration required for electronic data exchange systems to truly yield the benefits they offer the biopharmaceutical manufacturing industry. Sharing platform information and standard procedures and processes for the interactions between supply partners and biopharmaceutical manufacturers will result in quality being built in and will drive out non-value-added waste. Supply chain planning, understanding and management is required to support the growth and expansion of the sector. This report recognizes the need for consolidated forecasting and demand planning for sector-critical raw materials and services. For each of these initial areas of interest there seems to be very few current examples available to be shared.

Supply chain professionals from both sides of the Supply Partnership Management activity need to work in concert to assure regulators and explain the benefits of cross-industry simplification by standardization and the positive impact that it may have on quality and compliance. Such benefits will lead to the reduction of time to patient for both new products and the delivery of existing ones.

Recommendations

The recommendations for further work for the roadmap to consider are:

1. further work to develop the ways of working, collaboration and develop a culture of trust
2. development of an electronic data exchange as a process with standard applications across the industry
3. engagement with the regulators on areas of duplicate requirements and acceptance of developing standard practices
4. technology assessment of developments from Industry 4.0, how they apply to the biopharmaceutical industry and the potential for impact on the inbound supply chain
5. deeper assessment of the capacity to meet the growth needs of the industry in key areas such as the supply of critical raw materials (e.g. cell culture media components and specialist plastics for single-use systems) and services (e.g. sterilization and lyophilization) with consideration of cross-industry forecasting and demand planning to support the roadmap
6. as future production of biologicals becomes even more global, supply chains to support the industry continue to be distributed worldwide. The finished products are also distributed globally. Future editions of the roadmap should also consider supply chain mapping and the transportation and logistics of materials.

It is in the interests of all parties involved in Supply Partnership Management for it to be successful. As the sector develops, new relationships will form and evolve. New supply partners and biomanufacturers will appear through mergers, acquisitions and demergers and, as the level of supply partner integration increases, the lines of differentiation between supply partners and biomanufacturers will become less distinguishable.

Overarching next steps

Participation levels in this first edition of the roadmap demonstrate that the industry will openly share technology strategy and that organizations are broadly moving in the same direction with shared challenges. The development of the roadmap has highlighted the importance of collaboration to overcome challenges and to develop solutions that will benefit all stakeholders and, ultimately, our patients.

The first edition kick-starts the roadmap initiative and has imbued a sense of momentum to evolve to the next level of maturity and operationalize the roadmap.

The steering committee recommends several steps that the industry can take to move forward. The industry is identified as inclusive of all stakeholders (patients, biomanufacturers, suppliers, regulators, etc.).

These steps are overleaf.

Overarching next steps

1. **build awareness** of the biopharmaceutical roadmap and encourage engagement through proactive communication activities with industry public events, networks and within organizations
2. **engage with key industry organizations** and gather feedback from the industry to form a response to the roadmap, align efforts and consider funding routes
3. **identify collaboration opportunities** in response to roadmap needs to accelerate innovation initiatives and roadmap 'quick wins'
4. **develop and track industry analytics** to understand the ever-changing market trends and progress of innovation
5. **widen the participation** to engage key stakeholders, including regulators and academics, to effect the implementation of the roadmap vision
6. **broaden the scope** of the roadmap effort with new areas of focus and continued future editions
7. **nominate and recruit** subject matter expertise for future roadmap activities (e.g. industry benchmarking and tracking, trend analytics, collaborative projects, communications, regulatory interactions and/or input) for the roadmap's second edition process
8. **a significant cultural change** is required to support the innovation and new ways of working that will be considered in future editions. One aspect that was considered by academic contributors to the roadmap was education and training requirements. It is critical that the industry continues to have a well-educated and trained workforce alongside continued, disruptive, technology advances. Anecdotal evidence suggests that a training gap already exists between graduates and the needs of the industry and this gap is likely to widen as new technologies are implemented

Overarching next steps

9. **a global understanding of generic and specific skills** is required to understand the educational needs of the next generation. An outcome such as a skills roadmap would highlight the key technical and soft skills needed for individuals to be successful in the highly regulated, fast paced, biopharmaceutical manufacturing sector. This knowledge can then be shared broadly and adapted to the unique situations and opportunities available within individual countries and academic institutions
10. **given the broad skill** set needed for bioprocessing (including process development/engineering, manufacturing sciences, quality control, facilities, etc.), a range of backgrounds will be appropriate including chemical engineering, mechanical engineering, analytical chemistry, biology and IT at the BSc, MSc and PhD levels. While automation is certainly changing the way workers are contributing, the increasing complexity of new technology is likely to make the component of training even more important in the future
11. **also of importance is the method for implementing curriculum development.** Given limitations in time and resources, an international effort dedicated to online training could streamline the ability of students and trainers to understand and teach fundamental concepts. It is also critical to deliver hands-on training in laboratories, good manufacturing practice (GMP) and GMP-like environments. Many organizations around the world have excellent programs that can be leveraged to establish best practices.

This technology roadmapping effort is an evolving, dynamic and open process. We welcome comments from all industry stakeholders and look forward to continued growth in membership, further accelerating and broadening our industry impact. Please go to the BPOG website to learn how to become part of this world-wide effort for the biopharmaceutical industry:

<http://www.biophorum.com/category/resources/technology-roadmapping-resources/introduction/>

Appendices

Appendix A – Antitrust statement

It is the clear policy of BioPhorum that BioPhorum and its members will comply with all relevant antitrust laws in all relevant jurisdictions:

- All BioPhorum meetings and activities shall be conducted to strictly abide by all applicable antitrust laws. Meetings attended by BioPhorum members are not to be used to discuss prices, promotions, refusals to deal, boycotts, terms and conditions of sale, market assignments, confidential business plans or other subjects that could restrain competition.
- Antitrust violations may be alleged on the basis of the mere appearance of unlawful activity. For example, discussion of a sensitive topic, such as price, followed by parallel action by those involved or present at the discussion, may be sufficient to infer price-fixing activity and thus lead to investigations by the relevant authorities.
- Criminal prosecution by federal or state authorities is a very real possibility for violations of the antitrust laws. Imprisonment, fines or treble damages may ensue. BioPhorum, its members and guests must conduct themselves in a manner that avoids even the perception or slightest suspicion that antitrust laws are being violated. Whenever uncertainty exists as to the legality of conduct, obtain legal advice. If, during any meeting, you are uncomfortable with or questions arise regarding the direction of a discussion, stop the discussion, excuse yourself and then promptly consult with counsel.
- The antitrust laws do not prohibit all meetings and discussions between competitors, especially when the purpose is to strengthen competition and improve the working and efficiency of the marketplace. It is in this spirit that the BioPhorum conducts its meetings and conferences.

Roadmap intended use statement

This roadmap report has been created, and is intended to be used, in good faith as an industry assessment and guideline only, without regard to any particular commercial applications, individual products, equipment, and/or materials.

Our hope is that it presents areas of opportunity for potential solutions facing the industry and encourages innovation and research and development for the biopharmaceutical industry community to continue to evolve successfully to serve our future patient populations.

Permission to use

The contents of this report may be used unaltered as long as the copyright is acknowledged appropriately with correct source citation, as follows "Entity, Author(s), Editor, Title, Location, Year"

Disclaimer

Roadmap team members were lead contributors to the content of this document, writing sections, editing and liaising with colleagues to ensure that the messages it contains are representative of current thinking across the biopharmaceutical industry. This document represents a consensus view, and as such it does not represent fully the internal policies of the contributing companies.

Neither BPOG nor any of the contributing companies accept any liability to any person arising from their use of this document.

