

# AN EVALUATION OF Postapproval CMC Change Timelines

By Rob Harris, PhD, Meike Vanhooren, PhD, Kara Follmann, PhD, Beth Kendsersky, Timothy J.N. Watson, PhD, Melinda Imperati, S. Connor Dennis, PhD, and Roger Nosal

As the demand for accelerated access to medicines expands globally, the pharmaceutical industry is increasingly submitting regulatory applications in multiple countries simultaneously. As a result, Boards of Health (BoHs) are challenged with approving these applications in an accelerated timeframe and accommodating the submission of postapproval chemistry, manufacturing, and controls (CMC) changes that pharmaceutical manufacturers submit after implementing improvements or optimizations.

**A**mong global BoHs, variability in regulatory requirements and approval times for postapproval CMC changes has created an inordinately long delay between the first and last approval for a single CMC change for a pharmaceutical product. These long global approval timelines complicate supply chain management by delaying innovations that improve quality assurance and by increasing the potential for supply interruptions and shortages that impact patient access to products.

In this article, we describe the assessment of lag time for global regulatory approvals of postapproval CMC changes for multiple products over a three-year period. This approach incorporates all factors that influence the time for BoH approval as experienced in real-world situations and is relatively straightforward to calculate. It also allows for comparisons between companies and across different periods of time.

“In scope” were changes that required the most detailed BoH assessment in an impacted country (either by a notification or prior approval). For each country, the time required to achieve 90% probability of approval for a change represents the time between the first approval and each subsequent country BoH’s approval for

that change. We believe this represents the most relevant measure to assess the duration and impact on implementation and reflects the largest degree of complexity faced by industry to support postapproval CMC changes.

The results show that the time to achieve a 90% probability of approval for that change is  $\geq 24$  months in 63% of countries studied and  $\geq 36$  months in 15% of countries studied. In addition to delaying optimization of manufacturing and controls, these types of long delays for approvals discourage continuous process improvements for approved products.

We hope the results from this assessment stimulate adoption of the World Health Organization (WHO) Good Regulatory Practice (GRP) as well as implementation of International Council for Harmonisation (ICH) guidance that would improve the quality assurance of medicines for patients, decrease wait times with regulatory authorities, and reduce complexity and costs for industry.

## VARIABILITY OF BOH APPROVALS

The time it takes to achieve global regulatory BoH approvals of postapproval CMC changes varies considerably around the world. The assessment of how long it takes to achieve global approval for postapproval CMC changes provides compelling data to improve regulatory processes, as the expedited implementation of optimizations for manufacturing and control of products increases quality assurance for patients globally.

The WHO is driving implementation by BoHs of GRP, which will improve regulatory processes [1]. The risk of a change to patients is inherent to the change itself, not in which country it is being reviewed. On this basis, it seems appropriate that there should be greater global consistency in the regulatory processes, data requirements, and BoH assessment durations required to establish the suitability of a change.

Previous publications on this subject provide general information on BoH assessment timelines (e.g.,  $> 24$  months) [2, 3]. The

assessment described herein includes recent “real world” data to describe the increasing probability of approval over time after the first global approval for a particular change. Taking Kuwait as an example (using data in Table 2), after the first approval for a change (anywhere in the world), there is a 50% chance of approval of that change in Kuwait within 24 months and a 90% chance of approval within 43 months.

Postapproval CMC changes have several drivers. For example, a site of drug substance or drug product manufacture may be moved and/or added to effectively manage product inventory and ensure supply chain reliability; a manufacturing process may be modified to introduce innovation or efficiency; or it may be necessary to modify the drug substance or drug product specifications during the life cycle of a product to accommodate changes in regulatory standards or expectations.

For each BoH, the time for approval of a change is influenced by the local regulatory framework, i.e., statutory requirements, regulatory guidance and prioritizations, data standards and requirements, BoH assessment criteria, and resource capacity. Considering regulatory frameworks, many BoHs, such as the United States (US), European Union (EU), United Kingdom (UK), Japan, and Canada, have filing categories (i.e., do and tell; tell, wait, and do; and prior approval) that are aligned with the potential risk to critical quality attributes associated with safety, efficacy, and quality of the product.

Pfizer regulatory teams local to the impacted countries have reported that in some countries, the marketing application authorization (MAA) of a drug is granted based on a specific supply chain and that the introduction of an alternate source of supply after approval requires the submission of a new MAA (e.g., Bolivia, Hong Kong, Malaysia, Philippines, and Vietnam). In these countries, a secondary packaging site change or an active pharmaceutical ingredient (API) manufacturing site addition triggers a new submission equivalent to that required for approval of a generic drug or a line extension, whereas these site changes may be filed as a notification in the US and EU.

Additionally, Pfizer regulatory teams local to the impacted countries have reported that some rest of the world (ROW) countries require prior approval from a country that is also dependent upon prior approval in a third country. For example, Russia can require a sample at submission (based on approval from EU or other country). Subsequently, Armenia requires prior approval from Russia before the submission can be made in Armenia.

This sequence of submissions and approvals can significantly extend the time to final regulatory approval and is not in proportion to the risk of the change to patients. The WHO GRP contains the concept of mutual reliance and recognition, meaning that one or more countries can accept the assessment outcome from a reference country. Such reliance would reduce the time to approval in some countries and avoid the need for repeat assessment of a change that may have been reviewed, approved, and already be in distribution to patients in the first approving countries.

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## Long global approval timelines complicate supply chain management by delaying innovations that improve quality assurance and by increasing the potential for supply interruptions and shortages that impact patient access to products.

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The BoHs listed previously have well-defined data requirements; however, in the ROW, many countries have additional data requirements for the submission of a change. Due to the differences in the data (e.g., duration of stability data at time of submission) required by a BoH to support a postapproval CMC change, submission dates can vary by months or years between the first and last countries, due, in part, to the need to wait for additional and extraneous data. The ICH develops guidance for harmonization of data requirements for a postapproval CMC change [4]. However, these guidelines are not always interpreted or implemented consistently by country BoHs [5].

Increasing the capacity of a BoH, through implementation of WHO GRP and Good Reliance Practice, is a strategic focus of the WHO and the International Pharmaceuticals Regulators Forum [1, 6]. This implementation is designed to benefit all activities undertaken by the BoH, including the review of postapproval CMC changes, thereby optimizing BoH assessment times.

Improved alignment of regulatory processes will undoubtedly increase implementation of manufacturing optimizations, reduce the potential for drug shortages, lower the costs associated with managing inventory complexity, and encourage continuous improvement to increase quality assurance, particularly for approved older products [2, 3].

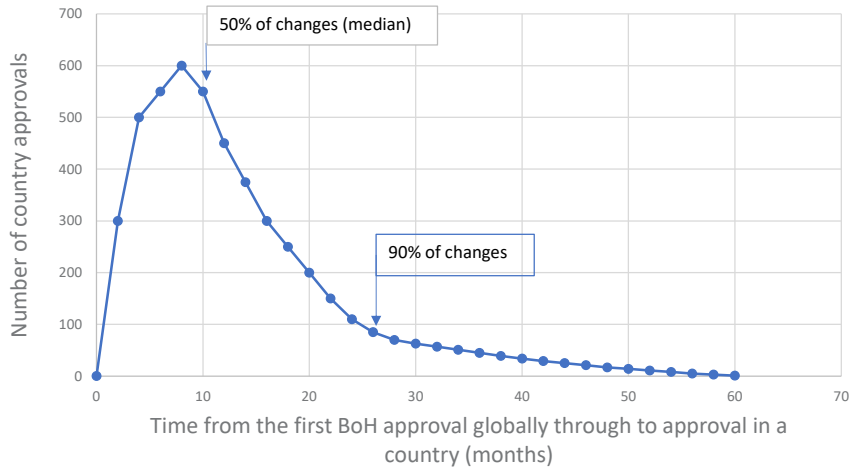
### METHODS

The total time to approval of a global postapproval CMC change was measured, using data from Pfizer’s GMP systems, as the time between approval in the first country to approval in each of the other countries impacted by that change. Table 1 shows a hypothetical example of how the assessment was performed. For each change, the time from first approval to approval in country A was recorded. Similarly, the time from first approval to approval in country B was recorded, and so on for all countries (represented by N) affected by the change. Then the durations were compiled for analysis and presented in the table.

**Table 1:** Hypothetical example of how an assessment was performed.

| Change Number | First Approval for the Change Anywhere in the World                                      | Approval in Country A | Duration from the First Approval of a Change to Approval for that Change in Country A (months) | Approval in Country B                                | Duration from the First Approval of a Change to Approval for that Change in Country B (months) |
|---------------|--|-----------------------|--|--|--|
| 1             | 1 Feb 2017   | 1 Feb 2018            | 12   | 1 Feb 2020   | 36   |
| 2             | 1 Jun 2019   | 28 Nov 2019           | 6  | 23 Nov 2019  | 18   |
| 3             | 1 Sep 2019   | 30 Nov 2019           | 3  | 28 May 2020  | 9  |
| N             | 1 Mar 2020   | 29 Jun 2020           | 4  | 24 Dec 2020  | 10   |
|               | Time after the first approval for a change, giving a 50% chance of approval in country A |                       | 5  | Time giving a 50% chance of approval in country B    | 14   |
|               | Time giving a 90% of chance of approval in country A                                     |                       | 10   | Time giving a 90% of chance of approval in country B | 31   |

**Figure 1:** Example of a skewed distribution.



For each country, only those changes with the highest assessment impact were included (e.g., Type II in the EU or a Prior Approval Supplement [PAS] in the US), as these would represent the greatest level of complexity for manufacturing and supply operations. In many countries, a prior approval category was required, but in other countries a notification of the same change was acceptable. BoH approval was based on either evidence of submission for a notification to a BoH or a BoH approval letter.

**Scope**

The scope of the assessment was for country approvals received in the calendar years 2018–2020. The first global approval for a change covered by one of these country approvals could have been received before 2018 and was needed for the calculations. On this basis, country approvals covering 2016–2020 were included in the analysis.

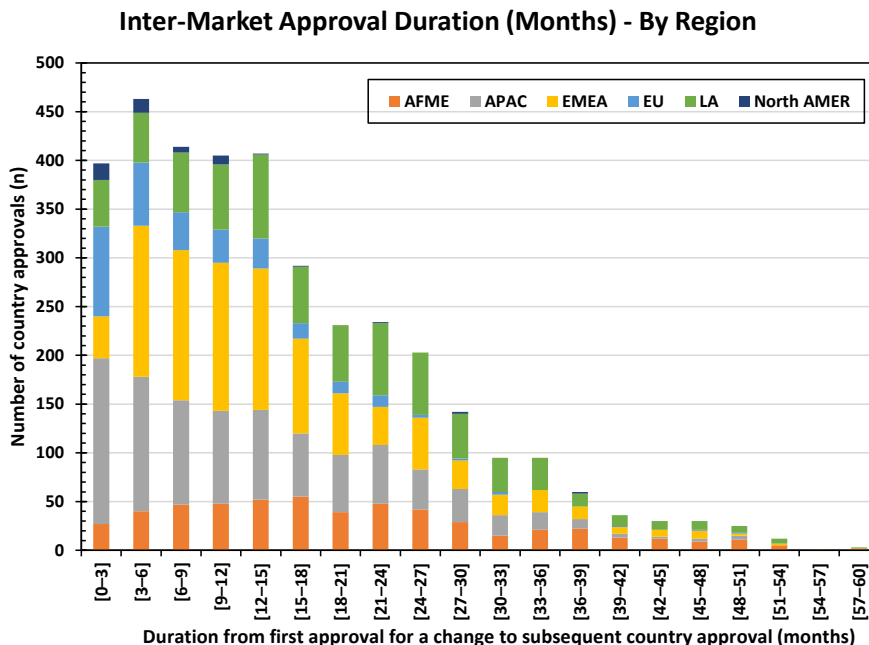
The countries impacted by a change should come from more than one geographical region to ensure a range of countries were involved. A country was in scope if it had 10 or more changes

approved during 2018–2020, which was the minimum number for which a percentage analysis is considered valid.

Data were collected for over 5,900 postapproval CMC changes that translated to 20,000 country submissions with approvals in 2016–2020. Of these, over 790 changes in over 3,575 country submissions covering 97 countries were in scope. Changes were considered out of scope if they did not use the highest assessment impact regulatory process (e.g., Type IA/IB/CBE30 or notification in a country with a prior approval category) or if the change was only applicable in a single region.

Because the duration to submit, review, and approve in each country was variable, depending on the type as well as on the BoH prioritization of change, two representative durations were determined: the duration after the first global approval for a postapproval CMC change to achieve a 50% probability of approval and the duration after the first global approval for a postapproval CMC change to achieve a 90% probability of approval. For each country, the durations measured showed a skewed distribution,

Figure 2: Consolidated view of all in-scope country durations (as described in Table 1) and color coded by region.



meaning that averages and standard deviations were not applicable. Figure 1 shows a hypothetical example of a skewed distribution and the indicative position of the duration giving a 50% chance of approval and a 90% chance of approval.

The duration required to achieve a 90% probability of approval of a postapproval CMC change in a country (after the first global approval for that change) reflects the increased complexity required to manage the supply chain for these products and the concomitant impact to supply chain reliability. The duration to achieve a 90% probability of approval of a change was chosen because capacity and inventory management can effectively meet extended durations for the remaining 10% of approvals through stock builds. The duration to achieve a 90% probability of approval is simple to calculate and can be comparable across global companies and through time.

## RESULTS

Figure 2 shows all the durations from first approval for a change to each country approval for that change (as described in Table 1) from the 3,575 in-scope country submissions. The skewed distribution is clear. The tail of approvals taking longer than 36 months can be seen. The long tail is the source of the greatest complexity for manufacturing operations.

For 47 of the 97 countries (48%), the time needed to achieve a 90% probability of approval of a change was  $\geq 24$  months but  $< 36$  months after the first BoH approval for that change. There was a 50% probability of approval of a change in 94 of 97 countries within 24 months and all within 36 months of the first BoH approval for that change.

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**Table 2:** Countries where the duration was  $\geq 36$  months after the first BoH approval for that same change.

| Country              | Region | Duration from First BoH Approval to Country Approval (months) | Data Points |
|----------------------|--------|---|-------------|
| Botswana             | AFME   | 51  | 14          |
| Jamaica              | LA     | 48  | 29          |
| South Africa         | AFME   | 45  | 24          |
| Kuwait               | AFME   | 43  | 49          |
| Oman                 | AFME   | 41  | 26          |
| Jordan               | AFME   | 40  | 31          |
| United Arab Emirates | AFME   | 40  | 45          |
| Iraq                 | AFME   | 39  | 39          |
| Morocco              | AFME   | 38  | 41          |
| Dominican Republic   | LA     | 37  | 72          |
| Curacao              | LA     | 37  | 43          |
| Namibia              | AFME   | 36  | 26          |
| Panama               | LA     | 36  | 61          |
| Kosovo               | EMEA   | 36  | 63          |
| Palestine            | EMEA   | 36  | 41          |

**Figure 3:** The cumulative percent of countries within each region against the duration needed to cover 90% of changes (as described in Table 1).

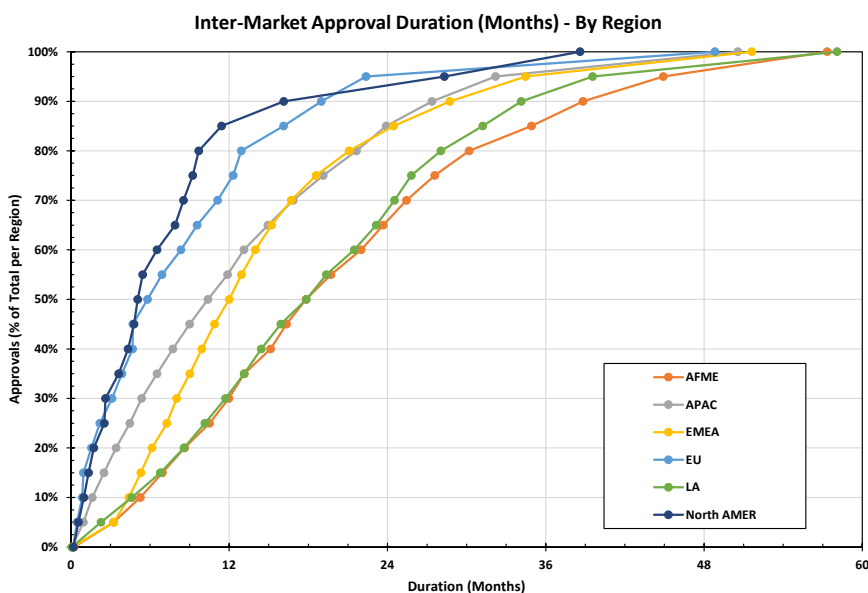


Table 2 shows the time needed to achieve a 90% probability of approval of a change (after the first approval for that change) for each of the 15 countries (15%) where the duration was  $\geq 36$  months after the first BoH approval for that same change. The durations were measured from first BoH approval for a change to that individual country's BoH approval for that change.

Figure 3 shows the cumulative percent of approvals by region against the number of months needed to achieve BoH approval after the first BoH approval for a change. It shows the spread of durations by region. For example, in North America, it takes approximately 16 months to achieve approval of 90% of submissions (after the first approval for that change), whereas in AFME it takes approximately 39 months to achieve the same milestone.

### DISCUSSION

It is well known that it can take several years to achieve BoH approval for a single postapproval CMC change [2, 3]. The results of this current assessment measure the duration for BoH approval on a per-country basis for approvals received over a three-year period. Included in the duration to approval for each country affected by the same change are the relative impact of the change requirements in addition to the first country, constraints on submission times, and the impact of queries on approval time and the BoH assessment duration.

The time from first country BoH approval for a postapproval CMC change through to achieving approvals in the other countries impacted by the same change is the time through which manufacturing and supply chain teams need to manage different product inventories. The longest durations are those associated with changes going through the most rigorous assessment category available within the country. Consequently, the focus of the analysis was on this subset.

The results show that there is a 50% chance of approval of a change in all but three of the 97 countries in less than 24 months after the first approval. These 50% generally do not represent the main source of supply management challenges. Hence, it was necessary to establish a measure that captured the changes that take longer to approve and are more likely to become supply chain management and reliability concerns. The duration to achieve a 90% probability of



**Table 3:** Examples of issues contributing to long durations and proposals to mitigate.

| Factors Contributing to Long Durations   | Proposals to Mitigate Prolonged Approval Times   |
|--|--|
| The stability data required at submission can vary from zero to six months in US and EU to > 12 months in some countries.  | Align requirements with global regulatory standards, e.g., ICH or a reference country.   |
| Changes cannot be submitted during an ongoing agency review of a change or a renewal (e.g., Brazil, South Africa), requiring sequencing and prioritization of submissions.   | Create capacity by adopting GRP. Match requirements to the implications for patients, enabling parallel submissions.   |
| The requirement for BoH approval regardless of the level of risk associated with a submission (i.e., no option for notifications). For example, a change covered by a notification in US or EU requires a new application in some countries. | Adopt a tiered approach such as that used in the EU or US.   |
| Duration of BoH assessment of changes.   | Reduce assessment durations by increasing capacity and adopting GRP, which includes mutual reliance and recognition, aimed at reducing workload for regulators and the time to approval.   |
| Multiple iterations of BoH queries, many of which are not scientifically focused.  | Improve risk-based approaches to regulatory reviews of postapproval changes, i.e., impact of change on product-critical quality attributes associated with quality, safety, and efficacy. In addition, consideration of mutual reliance and recognition, particularly when the change has already been effectively implemented in many countries globally. |
| BoH statutory framework, i.e., some BoH require a separate and specific licence for each manufacturing site. Consequently, any change in the manufacturing site requires a new submission rather than a postapproval change.                 | Legislation should be framed around the product rather than the site of manufacture.   |

approval of a change was chosen as the measure identifying supply chain management and reliability concerns.

In the dynamic global environment, the approval times for postapproval changes can be expected to change over time and may well differ between pharmaceutical companies based on different practices and approaches. Consequently, comparing results across companies and through time will establish an increasingly robust perspective of trends in global approval durations.

The results show that it can take over three years from approval in the first country to achieve a 90% probability of a country approval of that postapproval CMC change. Frequently during a three-year window, multiple CMC changes for a specific product will be submitted for global approval. Ostensibly, this significantly increases the complexity of managing multiple inventories and parallel supply chains for the same product simultaneously. This level of complexity increases the probability of affecting the reliability of supplies for every market.

Table 3 summarizes the factors that contribute to prolonged approval times based on experiences reported by Pfizer regulatory teams local to the impacted countries and proposes actions BoHs can implement to mitigate those prolonged approval times. The proposals are consistent with WHO GRP.

### Existing regulatory frameworks

In the 1950s and 1960s, the WHO published documents outlining how countries should set up a regulatory framework to control pharmaceuticals and ensure the safety of their subjects. In parallel, the certificate of a pharmaceutical product (CPP) process was developed, enabling certain regulatory authorities to confirm approval and thus serve as reference for the basis of approval for products

scheduled for import into other countries. Because regulatory legislation in different countries has developed independently, many different and sovereign approaches have evolved [7].

Reducing the prolonged duration for global approval of postapproval CMC changes will require improved alignment of data requirements; adoption of appropriate risk-based assessments that are proportional to the risk of a change to the critical quality attributes associated with product quality, safety, and efficacy; and alternatives to address BoH capacity constraints, i.e., mutual reliance and recognition, including cooperation between countries in evaluation.

These needs are all consistent with WHO GRP for regulatory oversight of medical products and “good reliance practices in regulatory decision-making for medical products” as well as the work of ICH covered in the mission statement and such publications as ICH Q12 “Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management” [1, 4, 8]. ICH Q12 provides a framework demonstrating how increased product and process knowledge can contribute to a more precise and accurate understanding of which postapproval changes require regulatory submission (Established Conditions). Postapproval change management protocols can be used to gain agreement among regulators about which requirements can be used to demonstrate acceptability of a change. In both cases, the level of reporting categories for changes can be agreed upon in advance.

### Categories of change

The US and EU (among others) have developed categories of change depending on the change type and associated risk, with a clear set of requirements and timelines [9]. Some of these

categories can be handled through notifications or annual reports rather than through prior approval applications. The EU has adopted procedures where the evaluation by one or more countries is recognized by other countries in the group (i.e., the Centralized, Mutual Recognition (MRP), and Decentralized (DCP) procedures).

In recent years, several countries have adopted the EU approach in terms of categories and filing types (e.g., South Africa, some Gulf countries) and introduced forms of cooperation and reliance to reduce the assessment burden across the group (e.g., the Gulf Cooperation Council, Association of Southeast Asian Nations). Unfortunately, some countries also retained their local requirements, and most did not implement the associated review timelines. Few ROW countries have published commitments to assessment durations. In some instances, the capacity of the regulator to process the changes submitted appears to be incompatible with reasonable assessment durations. Adoption of GRP would help balance resource and capacity in these countries.

Some countries have attempted to mitigate the long duration to BoH approval by introducing a process by which a special import permit can be requested when the time to BoH approval is impacting continuity of supply. However, organizing these permits demands additional time and capacity that should not be needed if the regulatory framework and associated infrastructure in those countries was consistent with GRP.


Approaches should be adopted that are consistent with GRP and provide alignment, clarity, and consistency of requirements, submission types, and appropriate regulatory timelines in accordance with risk-based assessments of postapproval CMC changes. Global adoption of GRP encourages manufacturing innovation by removing barriers to continuous improvement and ensures reliable and sustainable supply of medicines to patients globally.

## CONCLUSION

This exercise provided a comparative assessment of global approval times for postapproval CMC changes between 2018 and 2020. The results highlight the manufacturing and supply complexity associated with prolonged global approval times for each postapproval CMC change. In addition, the duration to achieve a 90% probability of approval of a change in a country represents the cohort of changes likely to be associated with supply issues and increased manufacturing complexity.

The finding that 15% of the 97 countries evaluated can take  $\geq 36$  months from first approval for a particular postapproval CMC change through to having a 90% chance of approval for that change in all other target countries represents a challenge for industry and the patients it serves. That the data obtained indicates that 63% of countries need  $\geq 24$  months to have a 90% chance of approval should also be considered to support advocacy in this area.

Implementing global best practices in medicines regulation to reduce the time from first to last approval for a global postapproval CMC change would minimize the cost of managing CMC changes for both regulators and industry. Such

implementation would also reduce waste, create a more robust supply chain, and increase the alignment of products dispensed to patients globally. 

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## About the authors

**Rob Harris, PhD**, is a Director of Harris Pharma Consultancy. Previously, Rob was a Senior Director in Global Regulatory Affairs, Chemistry, Manufacturing, and Controls at Pfizer Inc. He led a team overseeing manufacturing site changes for Pfizer's small molecule portfolio, having previously been responsible for the CMC dossiers supporting international submissions for new small molecule drug products. Prior to Pfizer, Rob spent two years at Wyeth Pharmaceuticals, responsible for the CMC dossiers supporting EU submissions for new small molecule products. Rob was Head of Regulatory Affairs in the UK office for Sanofi for nine years; during this time, he chaired the ABPI UK Regulatory Committee for one year. Rob earned his PhD in the pathophysiology of cerebral ischemia from the University of London.

**Meike Vanhooren, PhD**, has more than 25 years of experience in the pharmaceutical industry covering regulatory, manufacturing, and quality areas. She is based in Germany and has global responsibility for CMC. Her portfolio at Pfizer touches the complete product life cycle, from investigational new drug applications and investigational medicinal product dossiers for first-in-human clinical studies and new drug applications and MAAs through postapproval life cycle maintenance. Meike has extensive experience in drug development of accelerated programs as well as programs with novel technologies such as continuous manufacturing processes, including successful NDA/MAA approvals. She has been responsible for executing CMC strategies for manufacturing site changes and successfully completed more than 900 transfers impacting more than 22,000 licenses globally. Meike is engaged in discussions on ICH Q12 Lifecycle Management and ICH Q13 Continuous Manufacturing. She earned her PhD in organic synthesis of carbohydrate structures at the University of Hamburg, Germany.

**Kara Follmann, PhD**, is the Executive Director for Pfizer's Anti-Infectives, Hospital, Global Brands and Sterile Injectable CMC portfolio within Pfizer Global Regulatory Sciences and is based in Peapack, New Jersey. She has more than 20 years of increasing responsibility in the pharmaceutical industry, including extensive experience developing and implementing science- and risk-based approaches across the end-to-end product life cycle in support of innovative and established small molecule and biologic products across a broad variety of dosage forms, including combination products.

**Beth Kendsersky** was a Senior Director in Global Regulatory Affairs, Chemistry, Manufacturing, and Controls at Pfizer; she has retired. Beth led a team and managed global CMC clinical, commercial, and life cycle submissions and approvals for several small molecule drug products. Prior to Pfizer, Beth spent nine years at AstraZeneca Pharmaceuticals and held multiple positions within the regulatory affairs, CMC, and operations brand management teams. She spent 13 years at Sterling Winthrop Research Institute as an analytical chemist focusing on stability, method development, and CMC technical writing. Beth earned her associate degree in medical technology from Dutchess Community College in Poughkeepsie, New York, and her BS in chemistry at the State University of New York at Albany.

**Timothy J.N. Watson, PhD**, joined Gilead in 2023. Previously he was Lead for Pfizer's CMC Advisory Office, a collection of global Pfizer technical and regulatory experts who provide guidance and direction to project teams to mitigate regulatory risk and integrate CMC policy with product strategies, while developing and advocating policy positions (internally and externally) in conjunction with QO. The Advisory Office includes in region team members to support AFME, LATAM, A-Pacific portfolio execution, and CMC policy, including Pfizer's China's CMC product portfolio team. In addition to Advisory Office responsibilities, Tim has been instrumental in development and implementation of Quality by Design, ICH Q12, and other initiatives and continues to advocate for global regulatory harmonization and mutual reliance serving as a PhRMA representative to several ICH Expert and Implementation Working Groups since 2009. Tim served as a PhRMA EWG member on the ICH Q11 regulatory guidance document for drug substance, Rapporteur for the ICH Q11 Q&A Starting Material IWG, PhRMA IWG member for the ICH Q7 Q&A team, and continues to serve as the PhRMA ICH Q3C EWG Lead. Recently, Tim has been nominated to serve as the PhRMA IWG/EWG lead for ICH Q9 revision (starting in 2020). Tim serves on the Board of Directors for the International Consortium for Innovation and Quality (IQ), Co-Chairs the ISPE Global Regulatory

and Quality Harmonization Council and is a member of the Regulatory Steering Committee. He was appointed as Pfizer's lead representative on the PhRMA Global Quality and Manufacturing Work Group (GQM WG). Tim has published numerous publications and presentations and received numerous awards for regulatory contributions including the AAPS Regulatory Section Recognition Award in 2014. He has been a member of ISPE since 2007 and currently serves on the ISPE International Board of Directors.

**Melinda Imperati** is an Associate Director at Pfizer Global Regulatory Affairs Chemistry Manufacturing & Controls in Peapack, New Jersey. She has 26 years of experience, with increasing responsibility in the pharmaceutical industry, including extensive experience in technical and regulatory project management in support of innovative and established products. She is currently accountable to ensure appropriate regulatory resource, strategy, timely submission, and approvals for manufacturing site transfers as well as the legal entity name changes associated with the Viatris sale.

**S. Connor Dennis, PhD**, is a CMC regulatory consultant for Pfizer. He is a research scientist with industry experience in drug product development and global CMC regulatory affairs along with an academic background in bioengineering, materials science, and regenerative medicine. He has spent over six years consulting as a CMC author and strategist, supporting the Pfizer Plant Network Strategy (PNS) group in postapproval CMC changes. In addition, he has served as a data analytics lead on the to assess and improve global regulatory approval forecasting.

**Roger Nosal** is a Principal Consultant with Roger Nosal PharmaCMC Regulatory Consultants and serves as Head of Regulatory Strategy for NGT BioPharma Consultants. For 12 years, he was Vice President and Head of Global Chemistry, Manufacturing and Controls at Pfizer, accountable for all global regulatory CMC applications for innovative products. From 2018 to 2023, Roger served as Rapporteur for the ICH Quality Discussion Group and has been a representative to several ICH Expert Working Groups and Implementation Working Groups since 1994. Roger was instrumental in developing and implementing QbD and was awarded the Pharmaceutical Discovery, Development and Manufacturing Forum Award from the American Institute of Chemical Engineers (AIChE) for outstanding contributions to advancing QbD in 2013. Roger's 41 years of experience includes 24 patents, 28 years in regulatory CMC, and 13 years as a medicinal and process chemist. He joined ISPE in 2007.

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