



18 February 2021 (Updated 28 June 2021)

An Industry Proposal: Recommendations to Support the Rapid Increase of Manufacturing Capacity for the Production of COVID-19 Therapeutics and Vaccines

Executive Summary

The unprecedented stress that COVID-19 has imposed on the global biopharmaceutical supply chain necessitates urgent action to implement flexible, but predictable, regulatory tools and approaches that will allow manufacturers to rapidly increase manufacturing capacity for the production of COVID-19 therapeutics and vaccines to meet global demand, as well as avoid or mitigate drug shortages for non-COVID-19-related products, without compromising patient safety or product quality. One of the common strategies’ manufacturers will use to increase capacity for the production of COVID-19 therapeutics and vaccines globally, is the post-approval¹ transfer of a biopharmaceutical product to additional facilities. The steps required to execute a post-approval site transfer, however, can present a number of potential regulatory bottlenecks that may hinder manufacturers’ abilities to rapidly increase capacity for COVID-19 therapeutics and vaccines.

The International Federation of Pharmaceutical Manufacturers and Associations (“IFPMA”), Pharmaceutical Research and Manufacturers of America (“PhRMA”), European Federation of Pharmaceutical Industries and Associations (“EFPIA”), Japan Pharmaceutical Manufacturers Association (“JPMA”), Medicines Australia, and The Association of the British Pharmaceutical Industry (“ABPI”), collectively referred to as the “Sister Associations,” greatly appreciate the steps that the International Coalition of Medicines Regulatory Authorities (ICMRA) and individual regulators have taken during the current public health emergency (PHE) to exercise appropriate science- and risk-based regulatory agilities to support the expedited development and review of COVID-19 therapeutics and vaccines. While we support these initiatives, we believe there are opportunities to build on regulators’ ongoing efforts to **(1)** further enhance current approaches to the regulatory oversight of post-approval manufacturing changes and manufacturing facilities, particularly with respect to site transfers; and **(2)** modify existing, as well as develop additional, regulatory tools and mechanisms that will allow

¹ For the purposes of this document, “post-approval” also refers to “post-authorization” such as in the context of therapeutics and vaccines that have been granted Emergency Use Authorization (EUA).

both industry and regulators to more readily adapt to and overcome challenges presented by COVID-19.

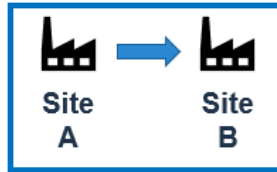
The Sister Associations have developed a number of globally focused, recommendations to address the regulatory challenges associated with manufacturing site transfers, that we believe, if implemented, would enable the rapid increase of manufacturing capacity for the production of COVID-19 therapeutics and vaccines. Our collection of recommendations includes near-term priorities for immediate implementation during the current PHE as well as long-term recommendations aimed at establishing a regulatory framework that can more efficiently and effectively respond to future PHEs. Our recommendations can be grouped into the following four categories:

- Streamlined Data Requirements (Near-term & Long-term)
- Regulatory Tools & Mechanisms (Near-term & Long-term)
- Collaborative Review, Reliance, & Recognition Practices (Near-term & Long-term)
- Harmonization through the International Council for Harmonisation (ICH)² (Long-term only)

The figure below illustrates the high-level steps in the post-approval site transfer process, as well as, at a categorical level, the steps in the site transfer process to which our recommendations apply.

² See International Council for Harmonization (ICH), <https://ich.org/>.

Steps for a Post-Approval Site Transfer (General Example)



Sister Association recommendations can be grouped into the following four categories:



Streamlined Data Requirements*^



Collaborative Review, Reliance, & Recognition*^







Regulatory Tools & Mechanisms*^





Harmonization^

If necessary, clear out existing products    




↳ Develop Transfer Plan: Gap Analysis, Equipment Changes, Develop Comparability Protocol, Develop and Execute Transfer Protocols, Cleaning Protocols/Validation for the new product, etc.    

↳ Engineering Runs

↳ Manufacture Product for Site B Data Generation: Process Validation, Method Validation, Stability Testing, Comparability, etc.    

Site B
Mfg.



↳ Compile Site A and Site B Data and Prepare Supplements/Variations (rolling)    

↳ Submit Supplements/Variations to Health Authorities (rolling); Respond to Queries (rolling)  

↳ Pre-Approval Inspection(s) (rolling)  

↳ Receive Approval of Supplements/Variations (rolling); Ship Product (rolling)  

↳ Activities to Support Post-Approval Commitments, as applicable    

***Near-term** – for implementation during the current PHE

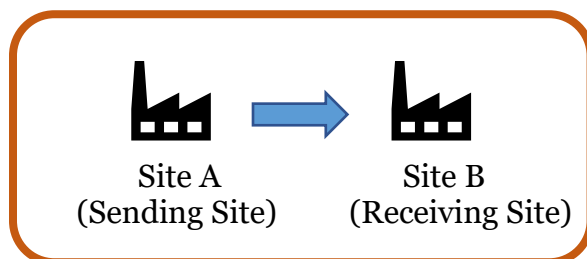
^**Long-term** – for implementation after the current PHE

I. Introduction

As manufacturers adapt to the current strain on the supply chain imposed by COVID-19, greater regulatory agility is needed to allow manufacturers to make risk-appropriate changes to facilities and manufacturing processes to ensure that an adequate supply of quality medicines and vaccines can reach patients. The unprecedented stress on the entire global biopharmaceutical supply chain – including raw materials suppliers, innovative biopharmaceutical manufacturers, generic drug and biosimilar manufacturers, contract manufacturing organizations, wholesalers, and distributors – necessitates urgent action to implement flexible, but predictable, regulatory tools that will allow manufacturers to rapidly increase manufacturing capacity for the production of COVID-19 therapeutics and vaccines to meet global demand, as well as avoid or mitigate drug shortages for non-COVID-19-related products, without compromising patient safety or product quality.

One of the common strategies manufacturers will use to increase capacity for the production of COVID-19 therapeutics and vaccines globally, is the post-approval transfer of a product to additional manufacturing facilities, including to sites belonging to other manufacturers (e.g., contract development and manufacturing organizations (CDMOs)). However, the steps required to execute a post-approval site transfer of a product can present potential regulatory bottlenecks that may hinder manufacturers' abilities to rapidly increase manufacturing capacity for the production of COVID-19 therapeutics and vaccines and ensure an adequate supply of quality biopharmaceutical products for patients around the world. To highlight a number of these regulatory challenges, in Section II we have listed, at a high-level, the steps for a post-approval site transfer of a product. In Section III, we describe science- and risk-based recommendations to address the regulatory challenges associated with manufacturing site transfers.

II. Steps for a Post-Approval¹ Site Transfer (Generalized Example^{2,3})



1. First, if necessary, **Site B**, the receiving site, **must “clear out”⁴ existing products** in advance of “receiving” the transfer of the COVID-19 therapeutic or vaccine. For each product that must be moved from Site B, there are several potential options which can be utilized individually or in combination with other options on this list:
 - The product could be transferred to a different facility; and/or
 - If possible, Site B may execute an emergency campaign to build up backstock of the product in an effort to mitigate the risk of a shortage while Site B focuses on the production of COVID-19 products; and/or

¹ While we have chosen to focus on post-approval site transfers for this illustrative example, the steps outlined here, with minor adaptations, largely reflect the same steps for the transfer and scale-up of a product from a clinical facility to the commercial manufacturing facility that will be utilized for commercial launch of the product.

² Site transfers can vary in complexity depending on a variety of factors, including, but not limited to: the type of product being transferred – small molecule vs monoclonal antibody vs vaccine; whether the transfer is of drug substance (DS) or drug product (DP); whether any changes to the manufacturing process will have to be made to accommodate the equipment at the receiving site, such as when a manufacturer scales up the process from clinical to commercial; whether the sending site and receiving site operate under different Quality Management Systems (QMSs), such as when the manufacturer that owns Site A is not the same manufacturer that owns Site B; and the Current Good Manufacturing Practices (CGMP) compliance history of the receiving site. Because it would not be practical to account for every variable in this document, we have chosen to utilize a generalized, product-agnostic example that illustrates the complexity of the site transfer process and allows for the identification of major challenges and pain points in the process.

³ Because site transfers can vary in complexity, there cannot be a one-size-fits-all approach with respect to regulatory expectations for these transfers. We urge regulators to apply a risk-based framework to manufacturing site transfers, including, for example, reducing the reporting category for a post-approval site transfer and waiving the pre-approval inspection (PAI), when appropriate.

⁴ This language is not intended to imply that facilities that manufacture COVID-19 therapeutics and vaccines will be used only to manufacture such products. Nor does this proposal intend to direct manufacturers to prioritize the production of COVID-19 therapeutics and vaccines over the manufacture of other products. We have included this step to highlight the challenges a manufacturer will face if it chooses to re-dedicate currently utilized capacity (e.g., a single or multiple manufacturing suites) at a facility to the manufacture of COVID-19 therapeutics and/or vaccines.

- Site B may, by working other regulators, seek to extend the shelf-life of the product in order to mitigate the risk of a shortage; or
 - Site B may determine that the product cannot be transferred to a different site and/or that an emergency campaign to build backstock cannot be executed and/or an extension of the product’s shelf life may not be appropriate. In this situation, production of the product would not continue and, if the manufacturer determined that the product would be at risk of shortage, the manufacturer would, as a matter of course, notify regulatory authorities of the shortage risk for that product.
2. Site A and Site B will then **develop a Transfer Plan** that will include, among other activities, a **gap analysis** between the two sites to determine whether equipment changes will be needed (if so, equipment will need to be ordered, installed, and qualified at Site B), determine whether process changes will be needed to accommodate differences in equipment between the two facilities, and identify and manage technical challenges. The gap analysis will inform the **development of the transfer protocols and the comparability testing plan**, as well as the development of any new protocols and procedures at Site B that will be needed to accommodate the new product (e.g., new cleaning procedures for the COVID-19 therapeutic or vaccine being transferred in order to ensure sterility). Site A and Site B will then **execute the transfer protocols**.
 3. Site B will then **execute “engineering runs”** of the transferred product to re-confirm the success of the transfer and identify and resolve any potential technical challenges that may arise.
 4. Site B will then begin **manufacturing the product to support activities/data generation for the regulatory filing**. As each manufacturing run is completed, Site B will execute the time- and resource-consuming processes of **process validation and analytical method validation**, initiation of real-time **stability studies**, as well as **execute the comparability testing** to demonstrate that the process at Site B is sufficiently comparable to the process used at Site A. Many regulatory authorities require comparability information in the regulatory filing to ensure that the currently manufactured product maintains the same efficacy and quality.

Under the current regulatory framework, the activities above can represent significant regulatory bottlenecks, as many regulators currently require the submission of all of this data in the supplement/variation⁵ before the regulator can/will review the filing. The current model often results in significant delays as many regulators are unfamiliar and uncomfortable with science-and risk-based approaches to streamline these activities. For example, traditional approaches to

⁵ In the United States, “supplement” refers to a prior approval supplement (PAS), Changes Being Effected in 30 days supplement (CBE-30), and Changes Being Effected immediately supplement (CBE-0). In other markets, a submission to make a change to a marketing authorization application is called a “variation.”

process validation can take six or more months to complete. In addition, many regulators require the submission of 12 or more months of real-time stability data and will not allow manufacturers to utilize accelerated stability testing, modeling, extrapolation, and/or prior knowledge as surrogates for real-time testing.

[From this point forward, Site B will continue to manufacture the product at-risk in order to build inventory so that the product is ready to ship as soon as the manufacturer receives regulatory approvals of the relevant supplements/variations.]

5. As Site B data become available, Site A and Site B **data will be compiled and supplements/variations for each market will be prepared**. Because of the different data requirements for each regulator, additional studies may have to be conducted for certain markets, therefore data will become available on a rolling basis. Consequently, and due to resource limitations, manufacturers will prepare the supplements/variations on a rolling basis.

Divergent data requirements can add substantial lead time to the post-approval site transfer process and significantly increase regulatory burden to manufacturers.

6. Once prepared, **supplements/variations will be submitted to health authorities in each market on a rolling basis**.⁶ Manufacturers can then expect to receive and respond to a number of queries from regulators regarding each submission. There is no harmonized or streamlined process for submitting queries to manufacturers, so applicants must often respond to multiple requests per health authority. Not only does this add significant regulatory burden to manufacturers but it can also delay the overall post-approval site transfer process.

In addition, regulators do not have consistent time commitments for the review of supplements/variations. For example, some health authorities could take years to review a supplement/variation, whereas in the U.S., the FDA has a 4-month review commitment for prior approval manufacturing supplements and, for CBE-30 supplements, the applicant must wait 30 days after submission before distributing the drug product made using the change (provided FDA does not object to the change during the 30 days after submission). FDA has among the fastest review commitments in the world, but even these timelines may be insufficient to meet the needs of the current PHE.

Further, some health authorities will only allow for the review of one variation per product at a time. This can substantially interfere with a manufacturers' ability to add facilities or change the facility where a product is being made,

⁶ Note that certain markets will only allow a sponsor to submit a variation for a change after the sponsor has received approval in a "major" market. This further delays overall timelines for the global implementation of post-approval changes.

and/or make changes to the product itself, in a timely manner and can risk shortage of that product in the market that has this regulatory mandate.

7. For site changes or additions, many health authorities will require that the “receiving site” (i.e., Site B) **undergo a pre-approval inspection (PAI)⁷ before the supplement/variation can be approved.** Given the global nature of the biopharmaceutical supply chain and travel restrictions in many parts of the world due to the pandemic, many health authorities may determine it will not be possible to conduct PAIs in a timely manner, particularly if extensive travel is needed to reach the facility to be inspected. If a health authority will not approve the supplement/variation until the facility can be inspected, patient access to the product may be delayed unnecessarily.
8. The manufacturer will then **receive approval of the supplement/variation and ship the COVID-19 therapeutic or vaccine** to the market for which the supplement/variation approval was received. Approvals will be received on a rolling basis given the different regulatory requirements and review clocks, therefore, product manufactured by Site B will be distributed in certain markets, before others, where there is an earlier regulatory approval of the supplement/variation.
9. Site B will **conduct activities to support post-approval commitments** in various markets, as applicable. Health authorities often have different post-approval expectations of manufacturers for the same post-approval change, adding regulatory burden to manufacturers.

III. Recommendations to Address the Challenges Associated with Manufacturing Site Transfers

To address the challenges in the post-approval site transfer process, and to help ensure the availability of sufficient manufacturing capacity for the production of COVID-19 therapeutics and vaccines, regulatory agility and alignment among regulators around the globe will be needed. We believe there are a number of regulatory bottlenecks that can be addressed, without compromising patient safety or product quality, through the adoption of science- and risk-based approaches to chemistry, manufacturing, and controls (CMC) data requirements for regulatory application review (including supplements/variations), current Good Manufacturing Practice (CGMP)⁸

⁷ As defined in the U.S.-EU MRA, “[p]re-approval inspections means pharmaceutical inspections of manufacturing facilities carried out in the territory of a Party as part of the review of an application before marketing approval is granted.” See United States-European Union, Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices, Chapter 1, Article 1.

⁸ As defined in the U.S.-EU Mutual Recognition Agreement (MRA), GMPs “means systems that assure proper design, monitoring, and control of manufacturing processes and facilities, the adherence to which assures the identity, strength, quality, and purity of pharmaceuticals. GMPs include strong quality management systems, obtaining appropriate quality raw materials (including starting materials) and

inspection and facility assessment programs, and the utilization of certain regulatory tools and mechanisms to increase efficiencies for both manufacturers and regulators.

To further address regulatory bottlenecks associated with site transfers, health authorities will need to work together to establish short-term regulatory alignment through international coalitions (e.g., ICMRA). Regulators will also need to come together to establish, enhance, and/or expand collaborative review and mutual recognition agreements to create efficiencies for both regulators and manufacturers throughout the current PHE. To create a global regulatory infrastructure that is better equipped to handle the challenges the world will face during a potential future pandemic, in the long-term, regulators will need to collaborate with industry stakeholders to develop harmonized guidelines through ICH that allow for appropriate regulatory agilities, as well as take steps to align regulatory frameworks to ensure both regulator and industry resources are devoted to the issues most critical to public health.

The Sister Associations have developed a number of science- and risk-based recommendations that we believe, if implemented, would enable the rapid increase of manufacturing capacity for the production of COVID-19 therapeutics and vaccines to help ensure an adequate supply of quality products for patients, while also mitigating, to the best of industry's ability, shortages of non-COVID-19 products.⁹ Our collection of recommendations includes both near-term priorities for immediate implementation during the current PHE and long-term recommendations aimed at establishing a regulatory framework that can more efficiently and effectively respond to future PHEs. Our recommendations can be grouped into the following four categories:

- Streamlined Data Requirements (Near-term¹⁰ & Long-term¹¹)
- Regulatory Tools & Mechanisms (Near-term & Long-term)
- Collaborative Review, Reliance, & Recognition Practices (Near-term & Long-term)
- Harmonization through ICH (Long-term only)

packaging materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.” See United States-European Union, Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices, Chapter 1, Article 1.

⁹ The risk-based regulatory agilities described below should be applied to COVID-19 therapeutics and vaccines as well as products that have been displaced (or otherwise impacted) to enable the manufacture of COVID-19-related products.

¹⁰ Intended for immediate implementation and applicable throughout the current public health emergency.

¹¹ Presented as a long-term solution to establish a regulatory framework that can more efficiently and effectively respond to future public health emergencies.

Specific Recommendations

The Sister Associations and our respective member companies greatly appreciate the steps regulatory authorities have taken, both prior to and during the current PHE, to improve the post-approval change (PAC) review process, including the development of the ICH Q12 Guideline.¹² The Q12 guideline will be critically important in improving the efficiency in managing PACs across global supply chains and significantly lowering the global regulatory hurdles manufacturers face when taking steps to modernize their manufacturing processes.

While the Sister Associations support regulators' current efforts, we believe enhancements to current approaches should be rigorously explored in order to enable the continuity of the global drug supply chain, facilitate the increase of manufacturing capacity for COVID-19 products, and help ensure timely patient access to medicines and vaccines. In addition, recognizing that legal and regulatory limitations exist in the various jurisdictions, we encourage regulators to exercise risk-appropriate regulatory agility whenever possible, and to the extent feasible, within current jurisdictional legal frameworks. Our specific recommendations are as follows:

- **Streamlined Data Requirements** (Near-term & Long-term)
 - The Sister Associations request that regulators allow manufacturers to extend the shelf-life of products in shortage or at risk of shortage by utilizing accelerated stability testing, predictive stability modeling, extrapolation, and a sponsor's own prior knowledge.
 - The Sister Associations recommend that regulators streamline stability testing requirements by reducing the timelines for real-time stability testing, focusing only on patient-centric (clinically relevant) critical quality attributes (CQAs) for stability testing, allowing for the submission of non-site-specific data, and increasing the acceptance of accelerated stability testing for biopharmaceutical products.
 - During the COVID-19 pandemic, we encourage regulators to work through ICMRA to rapidly align on expectations and requirements for streamlined stability testing and communicate these expectations and requirements to industry.
 - The Sister Associations urge regulators to more consistently allow manufacturers to utilize alternate process validation approaches for biopharmaceutical products, such as decoupling DS and DP validation activities, concurrent validation, acceptance of United States Pharmacopeia (USP)-, Japanese Pharmacopeia (JP)- and European Pharmacopeia (EP)-compliant excipients, and

¹² See ICH Q12 (Step 4): Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Nov. 20, 2019), https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1119.pdf.

appropriately leveraging prior knowledge to defer the submission of certain process validation data to post-approval.

- During the COVID-19 pandemic, we encourage regulators to work through ICMRA to rapidly align on expectations and requirements for the utilization of alternate process validation approaches and communicate these expectations and requirements to industry.
- The Sister Associations urge regulators to exercise risk-based regulatory agility for the data requirements for a supplement/variation for a site change or addition (i.e., allow for a supplement/variation to be submitted and approved without the normal package of stability and validation data – some data will be provided in the submission and the remaining data can be provided post-approval via other mechanisms, such as in an Annual Report (AR) or held within the firm’s pharmaceutical quality system (PQS)).
 - During the COVID-19 pandemic, we encourage regulators to work through ICMRA to rapidly align on these data requirements and expectations for the submission of a supplement/variation for a site change or addition and communicate these data requirements and expectations to industry.
- The Sister Associations request that regulators allow manufacturers to conduct comparability testing that focuses only on critical attributes that may be impacted by the site transfer (e.g., process changes made due to differences in equipment) and that utilize a limited number of lots for comparability testing.
 - During the COVID-19 pandemic, we encourage regulators to work through ICMRA to rapidly align on expectations and requirements for risk-based approaches to comparability testing and communicate these expectations and requirements to industry.
- **Regulatory Tools & Mechanisms** (Near-term & Long-term)
 - The Sister Associations urge all regulators to begin conducting voluntary “virtual inspections”¹³ with the consent of the inspected manufacturer. We further urge regulators to share lessons learned and work together to align on best practices for virtual inspections.
 - The Sister Associations suggest that regulators work with industry to develop an approach to the pre-qualification of standby facilities (i.e., potential future manufacturing sites for a single product or group of products) prior to the submission of a regulatory

¹³ The term “virtual inspection” applies to inspections that are performed off-site through the use of enhanced communication and information technology to fulfil a legal requirement of an on-site inspection. The only difference is that the inspector is not physically present. See IFPMA, “Points to Consider for Virtual GMP Inspections – An Industry Perspective,” (Jul. 2020), https://www.ifpma.org/wp-content/uploads/2020/07/Best-Practices-for-Virtual-Inspections_vF.pdf

application (i.e., preliminary inspection and preliminary tech transfer to allow for an expedited regulatory review and inspection strategy).

- The Sister Associations urge regulators to expedite the regulatory review of manufacturing supplements/variations for certain PACs (e.g., changes to materials sources, including API; changes to manufacturing or testing sites).
 - During the pandemic, we further encourage regulators to align on supplement/variation review timelines for COVID-19 therapeutics and vaccines.
 - The Sister Associations request that regulators more consistently apply a risk-based framework to manufacturing site transfers, including, for example, reducing the reporting category for a post-approval site transfer and waiving the PAI, when appropriate.
 - The Sister Associations request that regulators allow manufacturers to utilize the reporting categories for the PACs listed in the (Step 4) ICH Q12 Guideline and Annexes for the purposes of reporting PACs during the PHE.
 - The Sister Associations request that regulators create a regulatory pathway that allows a manufacturer to utilize a single submission (e.g., PAS) for a PAC that impacts multiple products and/or multiple sites.
 - The Sister Associations request that regulators allow manufacturers to utilize generalized multi-use post-approval change management protocols (PACMPs).
- **Collaborative Review, Reliance, & Recognition Practices** (Near-term & Long-term)

To the extent possible, and within the legal framework of each jurisdiction, the Sister Associations strongly encourage regulators to:

- Establish collaborative review arrangements (e.g., ACCESS, Project Orbis) for the review of supplements/variations for PACs for COVID-19 therapeutics and vaccines, as well as for products impacted by the pandemic. Regulators that participate in collaborative review arrangements should also strive to align on a unified set of queries for each PAC. In doing so, manufacturers will only have to develop one set of responses per query which can then be easily provided through each regulator's specific process or electronic platform (i.e., manufacturers can more or less copy-paste the same response into each regulator's system which reduces resource and regulatory burden for the applicant).
 - Alternatively, or in addition, cohorts of certain identified regulators should adopt reliance practices¹⁴ for PACs for COVID-19 therapeutics and vaccines by a health authority

¹⁴ Reliance models are voluntary and at the discretion of each regulatory authority and must be consistent with applicable local law.

with appropriately stringent standards. This could more realistically and feasibly be done by region (e.g., Latin America).

- Adopt reliance and/or recognition practices wherein certain identified regulators agree to accept the regulator-issued queries and associated manufacturer responses pertaining to the review of a supplement/variation by health authorities with appropriately stringent standards.
 - Develop and/or expand existing reliance practices and mutual recognition agreements for inspections of facilities manufacturing COVID-19 therapeutics and vaccines.
 - Industry strongly recommends that such reliance practices and recognition agreements include virtual inspections.
 - Utilize collaborative review, reliance practices, and/or mutual recognition agreements to alleviate resource strain such that regulators that currently only allow one variation per product to be reviewed at a time can allow the review of multiple variations per product at a time, to the extent possible.
- **Harmonization** (Long-term)
 - The Sister Associations request that regulators work with industry to develop and/or revise harmonized guidelines (e.g., through ICH) that reflect science- and risk-based approaches to stability testing, process validation, comparability testing, the establishment of patient-centric specifications, etc.
 - The Sister Associations applaud the ICH Assembly's recent endorsement of the revision of the Q1 Guideline series and Q5C, as well as the revision of Q6A and Q6B. Revision of these guidelines should be initiated as soon as possible.
 - Finally, the Sister Associations urge regulators to fully implement ICH Q12 and strive for additional alignment and efficiencies to minimize any divergent regulatory requirements or processes related to the management and evaluation of post-approval manufacturing changes.

IV. Conclusion

The Sister Associations believe the recommendations described in this proposal will be critical for regulators to implement during the current PHE to help both regulators and manufacturers overcome the challenges presented by COVID-19 and ensure timely patient access to quality medicines and vaccines. The Sister Associations also believe that many of these recommendations will be applicable after the pandemic and should be considered for long-term implementation in order to increase resource efficiencies both for regulatory authorities and the biopharmaceutical industry, as well as to ensure preparedness for future PHEs.

The Sister Associations stand ready to work with ICMRA, individual national regulatory authorities, and other stakeholders to advance and implement science- and risk-based regulatory agilities to enable the rapid increase of manufacturing capacity for COVID-19 therapeutics and vaccines as well as facilitate timely access to these critical products for patients around the globe.