READINESS FOR IMPLEMENTATION OF ICH Q2(R2) AND Q14

Industry Survey Results

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The International Council for Harmonisation (ICH) Q2(R2) and Q14 guidelines, finalized in late 2023, outline strategies for analytical procedure development, validation, and lifecycle management. As global implementation progresses, ISPE's PQLI® Analytical Method Strategy Team surveyed industry stakeholders in mid-2024 to assess readiness, identify opportunities, and highlight areas needing alignment between sponsors and regulators. Survey results indicate the new guidelines offer significant opportunities, though some challenges remain. Continued collaboration between sponsors and regulators is key to ensuring the guidelines have the greatest impact for improved and streamlined implementation and maintenance of analytical procedures.

The ICH guidelines Q2(R2) (a revision of Q2(R1), "Validation of Analytical Procedures" [1] and Q14 "Analytical Procedure Development" [2] reached step 4 of the ICH process on 1 November 2023. ICH regulatory members are expected to implement all harmonized ICH guidelines within their respective countries or regions. To date, the guidelines have been implemented by the European Commission (EC), US Food and Drug Administration (FDA), the Swiss Agency for Therapeutic Products (Swissmedic), the Egyptian Drug Authority, and the National Medical Products Administration (NMPA) in China. Argentina and Turkey have implemented Q14 and Saudi Arabia has implemented Q2. Historically, some non-ICH regions have adopted the guidelines as well.

To assess industry readiness for implementation and to understand challenges, opportunities, and overall preparedness of industry professionals, the ISPE-PQLI Analytical Method Strategy (ICH Q2(R2)/Q14) team conducted a comprehensive survey. The survey was conducted anonymously from 18 April to 15 July 2024, and received 201 responses. Of these, 57 provided answers to questions beyond demographic information and are discussed below. These responses, along with other optional free-text comments, are summarized, and the key findings and takeaways are presented.

SURVEY METHOD

The survey was developed by the ISPE-PQLI Analytical Method Strategy (ICH Q2(R2)/Q14) team to gauge awareness and implementation of the revision to ICH Q2 and the new guideline, ICH Q14. The survey contained 29 multiple-choice questions, with some requesting additional short comments. ISPE sent the survey by email to over 8,000 individuals in the ISPE database that met the criteria based on business category, job title, and job function. The email was sent on 18 April 2024 with the survey remaining open until 15 July 2024. During that period, the survey link was promoted on ISPE social media platforms, in an e-newsletter, and a blog post. Because the intent of the survey was to gather data from individual contributors rather than companies' consensus, responses were collected anonymously, and the companies of the responding individuals are unknown.

Survey Response Demographics

In response to the question "What role(s) does your company/organization have within the pharmaceutical industry?", survey respondents self-reported to represent companies in multiple sectors within the pharmaceutical industry (see Figure 1). Responding organizations spanned users of the Q2(R2) and Q14 guidelines, including pharmaceutical manufacturers (innovator, biosimilar, generics, and contract manufacturing organizations), raw material and excipient suppliers, contract analytical testing labs, and analytical equipment manufacturers, as well as CMC consulting and global pharmacopoeias.

In response to the question, "What is your role(s) related to

Figure 1: The diversity and representativeness of the survey sample by organization type.

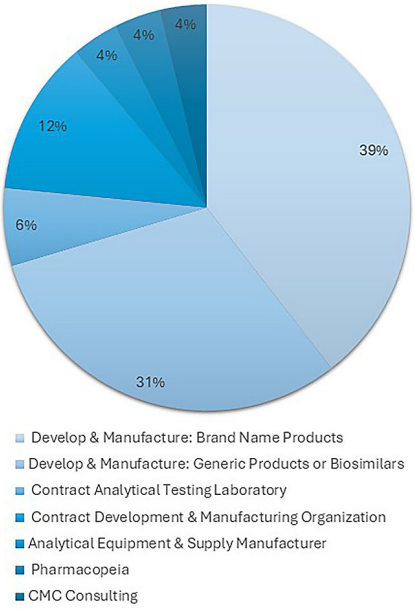
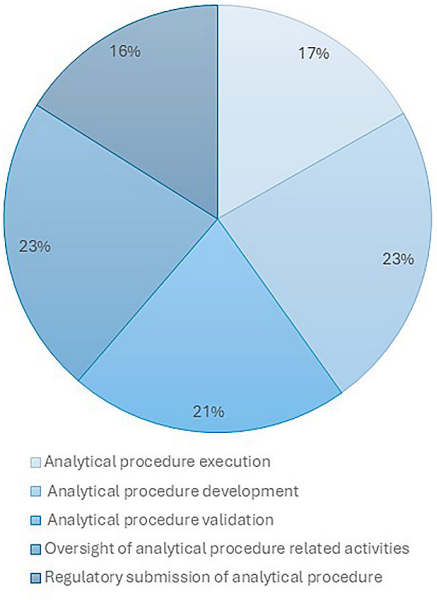


Figure 2: The distribution of job functions or responsibilities of survey respondents was spread across different areas within their organizations. Beyond the predefined categories, respondents also identified other relevant roles, showing the diverse expertise involved in analytical procedure work. These roles included: statistical support, IT, data analytics, and quality assurance.

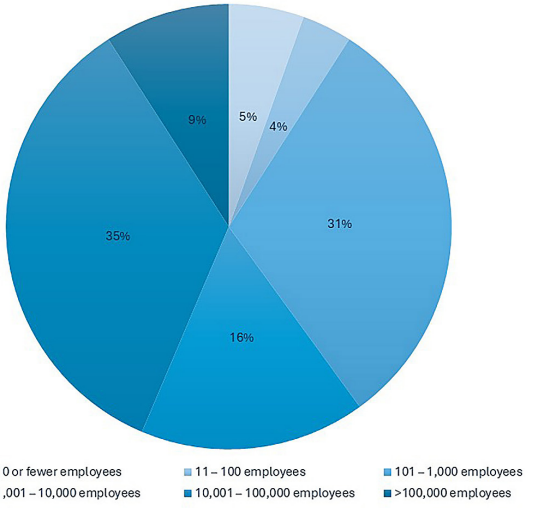


analytical procedures?", respondents reported that they held diverse roles within their companies, including analytical development, analytical procedure validation and/or lifecycle management, quality assurance, statistical analysis, regulatory, and IT (see Figure 2). A significant portion of participants were involved in method development, validation, and/or execution, reflecting the survey's focus on guidance related to the lifecycle of analytical procedures. Quality assurance and regulatory affairs professionals also constituted a substantial segment of respondents, reflecting that these guidelines impact technical, compliance, and regulatory elements of analytical procedure management.

Respondents represented organizations of varying sizes from fewer than 10 to over 100,000 employees (see Figure 3). The data indicate a balanced representation across small, medium, and large organizations, reflecting the ubiquitous nature of the guidance and that the survey findings are applicable to a wide range of company sizes within the industry.

The respondents reported that their companies manufacture and/or test products including small molecules, biologics, cell/gene therapies, vaccines, combination products, analytical equipment, excipients, and raw materials, siRNA therapeutics, active pharmaceutical ingredients, isotopes, and generic formulations (respondents could select more than one category). Figure 4 highlights the diversity of product types managed by respondent organizations. Small molecules were the single highest category reported (29%), however, there is notable representation of biologics, cell/gene therapies, and vaccines, as well as combination products, reflecting the industry's expanding focus on biologically derived therapeutics and complex modalities.

Figure 3: Company size distribution.

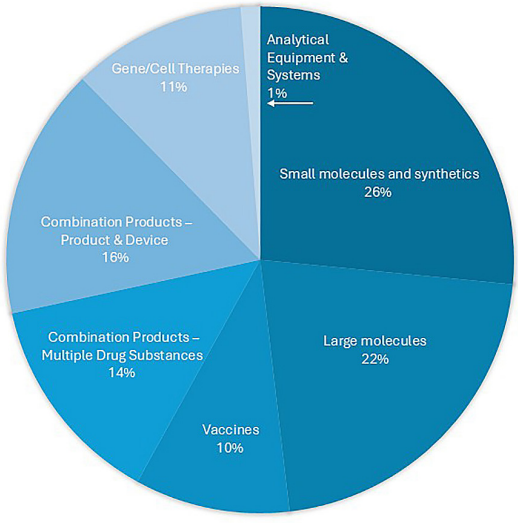


KEY SURVEY QUESTIONS AND FINDINGS

Opportunities, Challenges, and Perceived Risks in Implementing ICH Q2(R2)

Respondents were asked to provide feedback on the challenges and/or risks associated with implementing the revised Q2 guideline, particularly in light of the newly introduced elements. ICH Q2 has been a foundation of analytical method validation practice since its

Figure 4: Product types manufactured and/or tested by represented organizations.



initial publication in 1994. The revision of this guidance is widely recognized as having the potential to significantly impact ongoing operations. Responses varied from "none" (no risks or challenges) to addressing the many elements of Q2. Topics and scope included:

- **Confidence intervals**
  Setting acceptance criteria, evaluation, and reporting meaningful confidence intervals for accuracy and precision. The industry lacks sufficient guidance on how regulators expect criteria to be defined or data to be assessed—especially for variable methods with limited data availability. Appropriate use of statistical methods remains a concern.
- **Combined accuracy and precision**
  Uncertainty around how to establish meaningful acceptance criteria that integrate both accuracy and precision.
- **Regulatory acceptance of development and platform analytical procedure data**
  Risk that regulatory authorities may not accept data leveraged from prior validations or platform analytical procedures. There is a lack of clarity on the extent of data that can be leveraged from development studies.
- **Robustness**
  Evolving expectations for data quality and submission, particularly given the transfer of robustness-related topics to ICH Q14.
- **Multivariate analytical procedures**
  Challenges in developing initial models and meeting expectations for multivariate calibration.
- **Implementation**
  Questions around how to implement the flexibility afforded by ICH Q14. What level of operational control is required to utilize development data to support robustness? Lifecycle changes to analytical procedures may necessitate partial or full revalidation. Both companies and global regulators may be slow to adopt and implement these changes.
- **Application to legacy products**
  Unclear expectations for the application of revised concepts to legacy (approved) products, and the timing for global compliance with new product requirements.

Respondents shared positive feedback on the clarity and opportunities introduced by Q2(R2), with topics and scope including:

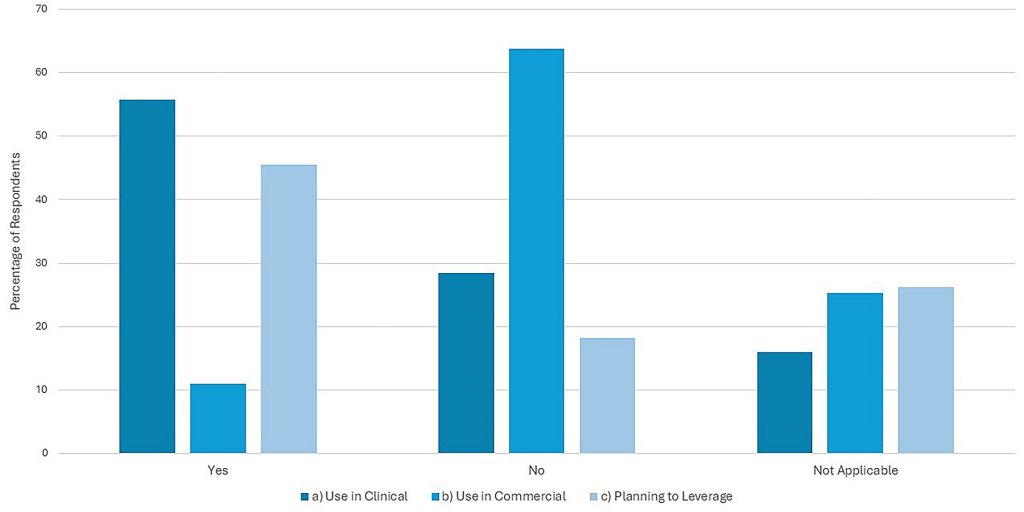
- **Wider variety of analytical procedures and modalities**
  Setting The guideline is directly applicable to a broader range of techniques and modalities.
- **Platform analytical procedures**
  Q2(R2) documents the concept of platform analytical procedures in guidance for the first time, which can enable increased efficiency and harmonization.
- **Prior knowledge and development data**
  Opportunity to leverage where appropriate and not repeat non-value-added studies, and also the opportunity to optimize time investment.
- **Utilization of science- and risk-based justifications**
  Opportunity to justify development and validation approaches versus prescriptive requirements.
- **Utilization of robustness data from development**
  Robustness testing in advance of validation should increase the speed and success rate of method validation.
- **Enhanced approaches to development and link to validation**
  Q2(R2) and Q14 enable increased acceptance of Quality by Design (QbD) approaches for analytical procedures.
- **Multivariate analytical procedures:**
  Clarity of application for techniques such as ICP-MS, FT-NIR, NMR, and direct application to biologics.
- **Combined accuracy and precision**
  General acceptance of the approach.
- **Lifecycle approach for analytical procedures**
  In combination with ICH Q14, validation is a component of lifecycle management. The link between development (Q14) and validation (Q2(R2)) is clear.
- **Clarity of application:**
  Examples in Annex 2 [1] illustrate direct application of ICH Q2(R2) concepts.

Additional insights on these challenges and opportunities are provided through responses to the questions discussed in this article.

Confidence Intervals in Validation

For accuracy and precision assessments in analytical procedure validation, ICH Q2(R1) states that confidence intervals around reported recovery/mean "should be reported" [3]. ICH Q2(R2) expands on this by stating that, "an appropriate 100(1-α)% confidence interval (or justified alternative statistical interval)…should be reported," and that "the observed interval should be compatible with the corresponding [accuracy/precision] acceptance criteria, unless otherwise justified" [1].

Figure 5: Adoption of platform analytical procedures in a) clinical development; b) commercial registrations; and c) plans to leverage common validation results for platform analytical procedures.



Respondents were asked if there were concerns with the updated recommendations for confidence intervals (CI) and the expectation that these intervals be compatible with acceptance criteria. The survey showed that 76% of respondents expressed the following concerns:

- 40% indicated that, due to a limited number of replicate samples in accuracy and precision validation, the confidence intervals may not be meaningful. They noted that this requirement may lead to an increase in the number of replicates needed for accuracy and precision validation.
- 21% stated that there is insufficient experience and data to set appropriate acceptance criteria.
- 16% stated that their organization lacks internal expertise to implement confidence intervals.
- 15% of respondents indicated no concern, noting that they had already implemented CI reporting.

One respondent elaborated in a free-text comment: "We are concerned about the increased risk of failures during validation against a criterion that we don't understand well enough to set meaningfully at this point. We are also concerned that, while we may be able to have scientific discussions about the results with some larger agencies who have more experience with this requirement, we may struggle with smaller global agencies who are also still learning—which could lead to reduced global harmonization vs the ICH goal of increased harmonization."

Considering that there are multiple reasons for industry to be concerned with the implementation of CI reporting as described in Q2(R2), increased dialogue will be necessary between industry and regulators. This could come about through the publication of the ICH training materials [4], webinars, and conference sessions.

Combined Approaches to Accuracy and Precision

ICH Q2(R2) allows for combined approaches for accuracy and precision [1]. The combined approach is also emphasized in the training material (Module 2) published by ICH on the Q2(R2)/Q14 guidelines [4]. Respondents were asked if their companies had already or were planning to leverage combined approaches to accuracy and precision.

The majority (58%) of the participants responded that they are already using or planning to use combined approaches, whereas 40% replied that they are using the conventional approach. "Target Measurement Uncertainty" was mentioned as an approach for the calculation of acceptance criteria. It was commented by one company that both approaches (combined or independent) are available as optional analytical tools. Two responses indicated that the combined approach was only applied to PAT methods. In addition, it was mentioned that challenges were experienced when combined approaches were not accepted by health authorities. One company mentioned that the combined approach was challenging for methods used for cell and gene therapies due to their inherent variability.

Platform Analytical Procedures

ICH Q2(R2) describes the use of platform analytical procedures for molecules that are sufficiently alike with respect to the attributes that the platform analytical procedure is intended to measure [1]. The survey asked several questions to respondents on their current and future use of platform analytical procedures.

Over 50% of respondents answered that they have utilized platform analytical procedures in clinical development (see Figure 5). However, slightly more than 10% have successfully been able to secure approval of platform analytical procedures with abbreviated

validation for commercial registration. When asked why companies had not been able to implement platform analytical procedures for commercial products, one respondent explained, the concept is "not implemented across entire agencies and for all modalities. [There is a] lack of understanding in health authorities and knowing what they are looking for."

Despite the current state, response to a follow-up question showed that those who are willing to implement for future commercial registrations increased to 45% (see Figure 5), a significant increase. However, only 10% responded that they will remain solely focused on clinical implementation for platform procedures (this response is not shown in the figure). Many analytical techniques were cited as having potential for implementation as platform analytical procedures, with the most commonly cited procedures used to analyze biologic products such as size-exclusion chromatography and cation-exchange chromatography.

Multivariate Analytical Procedures

Utilization of multivariate analytical procedures has grown significantly with the introduction of QbD in ICH Q8 over two decades ago [5]. The Concept Paper for ICH Q2(R2) and Q14 described that Q2 (R1) was not sufficient to demonstrate the suitability of multivariate methods and that the revision of Q2(R1) would include validation approaches for analytical procedures based on instrumentation that provides spectra across a frequency range [6].

In response to a survey question asking if the additional information provided on multivariate analytical procedures in ICH Q2(R2) and ICH Q14 provides greater clarity on what is expected for registration of these procedures, the majority (59%) of respondents think that additional information in Q2(R2) and Q14 on multivariate analytical procedures provides greater clarity for registration of these procedures. From written comments, respondents welcome a harmonized global standard for submission. Some respondents also pointed out that information in both guidelines remains relatively high level.

Real Time Release Testing (RTRT)

When asked if the additional information provided in ICH Q14 makes it more likely that their organization will implement RTRT, only 33% respondents agreed that additional information in the ICH Q14 guideline will lead to increased use of RTRT, and 32% disagreed. From written comments, respondents think that there is no clear incentive, and utilization of RTRT is mainly driven by product manufacturing requirements, control strategy, ICH Q13, and existing regional technical guidance. As one respondent put it, "We will use RTRT when it makes sense."

Analytical Procedures for Biological Products

The majority (54%) of the participants agreed that the additional information provided on analytical procedures for biological products in ICH Q2(R2) and ICH Q14 will have a positive impact on their review and approval process in the long run. Only 14% disagreed, while 7% did not respond, and 25% found the question not applicable. Comments were positive around the guideline's broad applicability to new modalities and complex technologies. Respondents were optimistic that a harmonized guideline would help to set a baseline of expectations, however, concerns were raised that broad acceptance by regulatory agencies might take a long time. Respondents also expressed concerns that more reviewer questions may result from the submission of information on complex topics such as design of experiments (DOEs).

Enhanced Approaches to Analytical Procedure Development

ICH Q14 describes enhanced approaches to analytical procedure development and introduces new regulatory tools for analytical procedure lifecycle management, which can enable post approval changes [2]. When participants were asked if their organizations were ready to implement these new approaches, 19% indicated that they were ready or had already implemented them. While this percentage is low, it was encouraging to see that 39% reported ongoing internal preparation activities for implementation.

When asked which elements of enhanced approaches or post approval change management tools that have been or will be implemented in analytical procedure development, respondents provided the information summarized in Figure 6.

Further insights into implementation challenges can be gained by examining individual elements more closely. For the elements of Analytical Target Profile (ATP), risk assessment, Design of Experiments (DOE), modeling, and analytical procedure control strategy, the reasons cited for lack of implementation or planning were highly consistent:

- Lack of global regulatory acceptance
- Lack of experience, subject matter exertise (SME), or training
- Increased cost

Two additional elements—Method Operable Design Region (MODR) and Established Conditions (ECs)—received significant feedback regarding why these have not been or will not be implemented. For MODR, respondents generally indicated that it offers very little value for lifecycle management re12%lative to the increased cost required to develop, validate, and maintain it. For ECs, the primary concern was lack of global regulatory acceptance. Respondents specifically noted that this concept was first introduced in Q12 [7], which reached Step 4 in 2019 but has yet to be implemented across all ICH regions. Additional concerns included lack of experience (SME), and increased cost.

The final topic in this section focused on the use of enhanced approaches to analytical procedure development, to better understand what types of procedures and what modalities were under consideration. Most of the responses indicated that chromatographic procedures were a primary focus area, with an additional mention of spectroscopic methods. As for modalities, the responses were broad and inclusive, covering both synthetic and biologic modalities, as well as combinations of the two.

Figure 6: Distribution of elements of enhanced approaches or post approval change management tools that have been or will be implemented in analytical procedure development. (Note: Percentages for each element are calculated based on the total number of responses.)

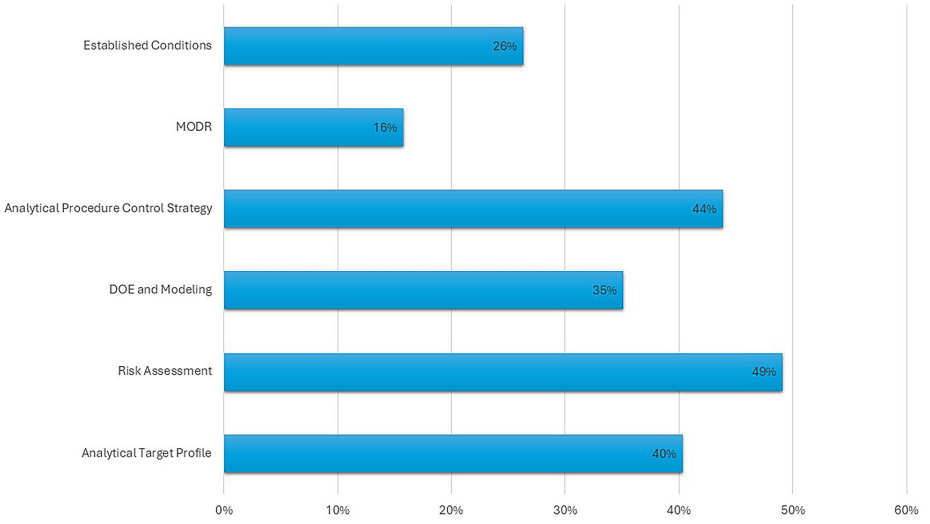
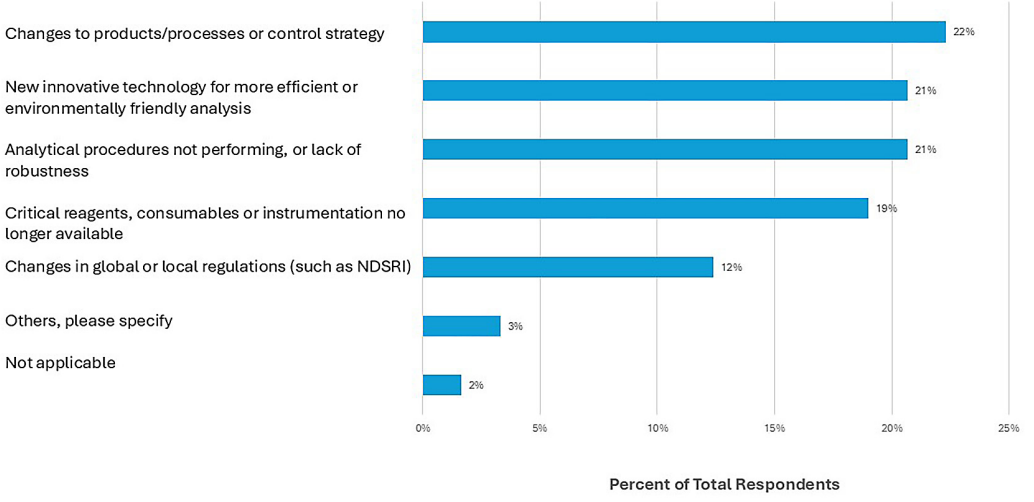


Figure 7: Major reasons for sponsors to make post-approval changes to analytical procedures (respondents were asked to select all that applied).



Regulatory Submission Experience

Respondents were asked if they had filed analytical procedures developed using enhanced approaches in commercial registrations. Only 12% responded affirmatively, while 56% stated they had not done so. The positive responses covered small molecule assay, impurity, and dissolution methods, as well as procedures for biologics submitted as part of a pilot program within the United States.

When asked whether development studies were described in commercial registrations, only 24% of respondents responded that either a development summary or details were provided (in addition to robustness studies). A summary of risk identification, justification of ECs, and description of performance characteristics and criteria were provided in one case, but several respondents acknowledged that details about method development—including elements of the enhanced approach—would need to be filed in the future once ICH Q14 adoption is more widespread.

Following initial submissions, sponsors may need to make post approval changes to analytical procedures. Potential drivers identified by respondents are presented in Figure 7. Additional feedback cited continual improvement considerations as well.

When asked whether analytical procedures had been filed in commercial registrations or post approval changes utilizing ICH Q12 lifecycle management concepts, only 11% of respondents indicated that they had done so. The types of analytical procedures included

those for biologics and small molecules. The Q12 tools utilized were Post Approval Change Management Protocols (PACMPs), Product Lifecycle Management (PLCM) documents, and the structured approach for post approval changes. Most submissions had been approved, primarily in the United States.

It is anticipated that applying principles described in ICH Q14 for analytical procedures can improve regulatory communication between industry and regulators and facilitate more efficient, scientifically sound, risk-based approval and post approval change management of analytical procedures. Approximately 50% of respondents cited examples where they would like to make changes to an analytical procedure but were hampered by regulatory constraints, as even minor changes require many regulatory approvals in multiple markets. This process is time-consuming and often necessitates duplicate testing, leading to significant supply chain impacts. In one comment, an analytical column was replaced due to failure, but the conditions were left unchanged due to the regulatory burden of achieving approval of the optimized procedure. In another comment, modernization of HPLC to UPLC systems (to shorten runtime and reduce environmental impact), or to switch from SDS-PAGE to capillary electrophoresis (CE), were not pursued due to perceived regulatory barriers.

When asked whether their company had a case study similar in format to the existing ICH Q14 case studies in Annex A—including elements such as the Analytical Target Profile (ATP), use of the enhanced approach to development, identification of Established Conditions (ECs), and implementation of a change—11 positive responses were received. Several respondents mentioned that they were in the process of filing with health authorities or intending to publish their case study.

In parallel with the survey described here, the ISPE PQLI Analytical Methods Strategy ICH Q2(R2)/Q14 team has described the challenges of analytical change management and how ICH Q14 concepts offer streamlining opportunities. (See Castle et al. article on page 30.)

DISCUSSION

The survey findings highlight the opportunities that pharmaceutical industry representatives identify in the finalization and adoption of ICH Q2(R2) and Q14. However, as with all incremental changes, challenges remain in implementing the guidelines and adapting to evolving regulatory expectations. In 2017, a survey was conducted by the IQ Consortium's Analytical Quality by Design Working Group focused on evaluating progress in analytical Quality by Design (QbD) [8]. While this effort predates the recent ICH revisions, it explored the use of Analytical Target Profiles (ATP), enhanced approaches to analytical procedure development, and regulatory experiences and outcomes from leveraging these options. In general, the majority of respondents had adopted some elements of analytical QbD approaches, but the potential of regulatory relief had not yet been realized.

One of the primary concerns raised in the current survey was the lack of global regulatory alignment regarding the acceptance of new strategies. Respondents expressed concern that some authorities may be hesitant to embrace platform analytical procedures and risk-based validation approaches, leading to inconsistencies in approval processes and potentially redundant work to meet expectations of different markets. Even when all ICH markets adopt these tools, there remains an opportunity for disharmony from non-ICH markets.

Concerns surrounding the ICH Q2(R2) requirements for assessing confidence intervals against corresponding criteria were commonly expressed. These concerns include uncertainty about setting criteria that will be deemed appropriate by a range of reviewers, the need for increased validation data required to meet statistical design requirements for more variable procedures or analytes, and a lack of internal statistical expertise to analyze and interpret the data. It is critical that industry and regulators converge on generally accepted practices for reporting confidence intervals in accuracy and precision studies to ensure meaningful and compliant implementation of this element of the guidance.

Companies expressed enthusiasm about ICH Q14's lifecycle management approach for post approval changes. However, many feel constrained by regulatory uncertainties surrounding the flexibility that could be gained through the use of enhanced development tools, such as the establishment of ATPs and MODRs.

Platform analytical procedures offer a promising avenue for efficiency gains. The ability to leverage existing data and prior knowledge across multiple products reduces redundancy in method validation and transfers [9]. However, full acceptance by health authorities remains a work in progress.

CONCLUSIONS

This survey provides valuable insights into the readiness and concerns of the pharmaceutical industry regarding the implementation of ICH Q2(R2) and Q14. Key takeaways include:

1. ICH Q2(R2) implementation presents challenges related to reporting requirements for confidence intervals, including the setting of meaningful acceptance criteria and the need for statistical expertise.
2. Significant opportunities exist in leveraging prior knowledge, platform methods, and enhanced validation strategies, and respondents are optimistic about implementing these tools.
3. Regulatory harmonization remains a key concern—particularly for platform analytical procedures and post approval changes—despite the availability of tools such as those presented in ICH Q12 [10]. Further implementation efforts are needed to ensure that global regulatory alignment on Q2(R2) and Q14 expectations.

Collaboration between companies, regulators, and industry organizations will be essential to ensuring a smooth and effective transition to these new guidelines. These efforts are already underway, with regulators and industry providing case studies and examples of successful implementations of new practices [11-14]. The findings presented here offer additional insights to direct future efforts toward areas of greatest impact and value.

Acknowledgements

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For more information about ISPE's PQLI, visit ispe.org/initiatives/pqli

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