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# PQLI ®: Current Status and Future Plans

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## Current Status

The International Society for Pharmaceutical Engineering (ISPE) launched its Product Quality Lifecycle Implementation (PQLI®) initiative in June 2007 to help industry find practical approaches to the global implementation of recent ICH guidelines. Through PQLI, ISPE is spearheading approaches to assist in the implementation of, in particular, ICH Q8(R1) (Pharmaceutical Development), Q9 (Quality Risk Assessment), and Q10 (Pharmaceutical Quality Systems). Key goals of PQLI include the provision of a technical framework required for the implementation of Quality by Design (QbD) in development and manufacturing environments.

PQLI started with highly interactive sessions in Europe and the USA aimed at gathering the views of both regulators and industry on key topics that needed the development of practical guidance to underwrite their successful implementation. It very quickly became clear that despite further elaboration in the revision to ICH Q8, there was an urgent need for examples and case studies that would assist in the understanding of three key concepts. These concepts were design space, control strategy, and how to designate critical quality attributes and critical process parameters.

Three multinational multidisciplinary teams were set up to address each of these topics. Through their deliberations, five papers were published in the June 2008 issue of the Journal of Pharmaceutical Innovation. Somewhat unusually, these papers were published with requests for comments. PQLI clearly recognizes that there is no one way to implement the ICH guidelines; rather, there are many perfectly satisfactory ways to address the concepts that are described in the guidelines. The Editors of the Journal and the authors of the papers were very heartened to receive constructive criticism and helpful comments from readers spread across all three ICH regions, including feedback from regulatory agencies and all sectors of the industry. The purpose of this editorial is to summarize elements of that feedback and to describe the plans that PQLI has for the next 2 years.

It was clear from the comments that everyone recognizes the enormity of the challenges that we face with the new QbD paradigm. It was also clear that unlike most conventional journals, PQLI had embarked upon its own continual improvement program. Without the papers and a mechanism for receiving and addressing feedback, there would be the risk of promoting less than optimal examples of QbD. This was not the case, and most respondents made many useful comments and are looking forward to future publications. The recommendations for such papers include numerous helpful suggestions. Feedback indicated that the initial papers require simplification with better linkage between the articles. Wherever possible, ICH terms should be exemplified, and new terms should be avoided. However, the real thirst is for PQLI to demonstrate how the concepts of the ICH guidelines translate into practical application in product realization, technology transfer, manufacturing operations, and batch release. Colleagues across our industry want to see the high level ICH concepts made real and practical. Clearly, case studies and rational examples are a great way of doing this, and the PQLI teams are actively developing such examples. These examples are

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all aimed at providing clear options demonstrating the many ways of implementing QbD. To address the concerns regarding regulatory expectations, PQLI will be clearer that its initiative is focused on the science and technology and not on regulatory policy. It is clearly recognized that the regulatory policy issues are addressed within ICH.

This valuable feedback provides clear direction for the future of PQLI. The first priority is to focus on the application of science and technology and risk-based approaches to product realization, manufacturing, and continual improvement. PQLI will realign to ensure all its activities are consistent with ICH guidelines and intentions. The teams have been privileged to receive feedback in this respect from members of the ICH expert working groups. We will capitalize upon that to ensure that we do the very best in explaining the meaning of ICH terms rather than inventing new ones or derivatives. As indicated above, there is an urgent need for simple, practical examples that show how companies are using quality by design principles in product realization and how that translates into manufacturing and release processes. You will see that PQLI is responding to that need in this issue of JPI. We are pleased to present a paper describing the application of quality by design principles to existing products. Presented within are processes, and examples, which demonstrate that quality by design principles are indeed applicable to existing products, are simple to apply to existing products and can result in significant business benefits. The paper provides three contrasting case studies which indicate a wealth of opportunities to improve processes for existing products through the use of science- and risk-based approaches and the subsequent business benefits and regulatory opportunities that can accrue.

## Future Plans

Over the next 2 years, PQLI will continue its many efforts to assist in the adoption and implementation of the ICH quality vision. The goal is to provide a set of resources useful to a broad spectrum of companies and the associated regulatory agencies. These resources will be useful to small, medium, and large innovator companies, as well as generic companies working on chemical and biotechnology active ingredients and products. PQLI will provide technical documents, news, views, and technical help in the form of conferences, training, and reference materials aimed at simplifying implementation of ICH Q8, Q9, and Q10 in both development and manufacturing environments. For established concepts, those that are already well defined by guidelines, and the ICH implementation working group, PQLI will continue to support and complement implementation topics with practical case studies, training opportunities, and extension of the understanding to global audiences. One of the first concrete examples of these activities will be the publication of a quality-by-design technical guide which will describe the continuum of development of a product through transfer to manufacturing and consideration of opportunities for continual improvement. It pulls together the three key topics of critical quality attributes and process parameters, design space, and control strategy and will show how application of quality by design to an existing product can be part of continual improvement. The technical guide will be responsive to the feedback received for the initial papers, will be practical and down to earth, and will link to many case studies and examples illustrating implementation. For newer concepts, PQLI will support further debate and discussion through papers, conference presentations, and workshops that involve both industry and regulators. PQLI members are already planning the structure and contents of two workshops in 2009, one to take place in Washington, D.C. in June and one to take place in Strasbourg, France in September. Consistent with the goal of describing the multiple ways that quality-by-design principles can be adopted, ISPE welcomes all contributions from both members and nonmembers who have ideas and examples that describe the practical application of the new ICH quality guidelines. ISPE is reaching out to other organizations; for example, PQLI activities were recently


**Fig. 1** PQLI process to generate technical implementation guidance

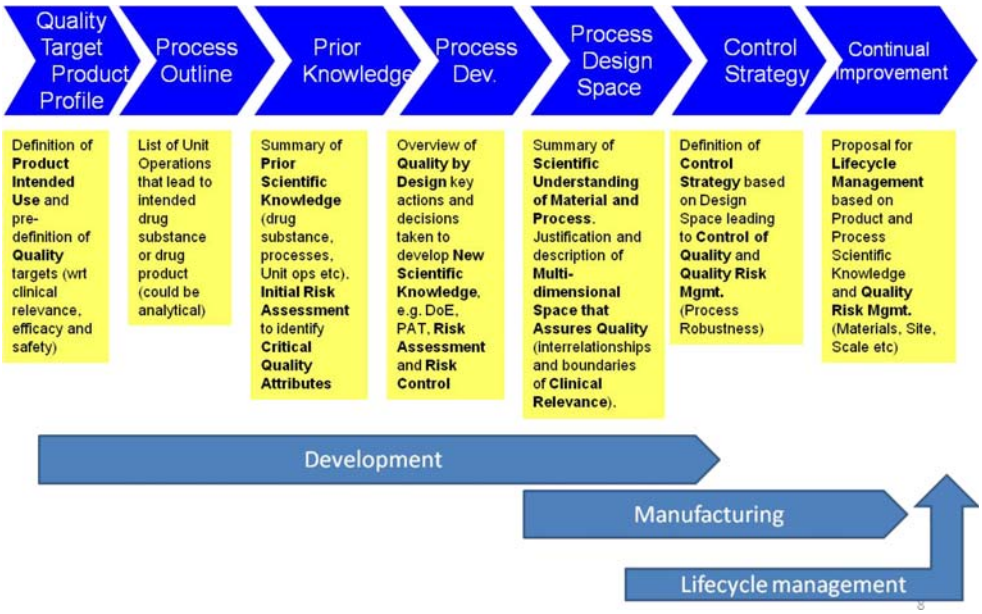


**Fig. 2** Process flow for quality by design

presented to colleagues in the process analytical community at the annual International Forum for Process Analytical Chemistry (IFPAC) Conference in January 2009, in Baltimore, MD, USA and also to European pharmaceutical scientists at the European Federation of Pharmaceutical Sciences at their June 2009 meeting in Nice, France.

The evolutionary process that PQLI will follow is shown in Fig. 1. PQLI work products will generally begin with a workshop, usually with both Industry and Regulatory participation, which provides opportunities for new and existing members to participate in the development of implementation guidance. Figure 2 illustrates the basic flow of quality by design which will be the foundation for all future topics. Even from this figure, it can be seen that there are many areas that would benefit from further discussion.

## Conclusion

ISPE's PQLI initiative is not a destination; it is a global journey. While quality-by-design is not new, and certainly is not a universal panacea, its intentions of encouraging industry to develop a greater understanding of its products and manufacturing processes are worthy indeed. Industry has an obligation to provide the patient with a quality product, and quality-by-design will improve the ability to do just that with improved efficiency. JPI is pleased to be able to support such an important initiative and will be pleased to receive manuscripts that support the goals and principles of PQLI. PQLI is also an interactive journey. If you have any comments or contributions you wish to make to PQLI, please feel free to e-mail PQLI@ISPE.ORG.