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The Birth of a Journal

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Preface

The Birth of a Journal

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1. Introduction

The *Journal of Applied Pharmaceutical Regulatory Science* has been almost 20 years in the making and is being launched to address a gap in the academic journal ecosystem, to publish peer-reviewed research papers and other articles on the topic of applied pharmaceutical regulatory science.

Regulatory science is defined by the United States Federal Drug Administration (FDA) as

> *"the science of developing new tools, standards, and approaches to assess the quality, safety and efficacy of drug products,"*

while the European Medicines Agency (EMA) notes:

> *"Regulatory science refers to the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and* ***applied biomedical and social sciences*** *and contributes to the development of regulatory standards and tools."*

This new journal's origins stem from 2005, when the Pharmaceutical Regulatory Science Team (PRST)[1] was founded at the Dublin Institute of Technology (DIT) by the authors of this article, in response to a call for a paradigm shift in quality from the international regulatory community.

Since then, the PRST has actively engaged with global industry and regulators to address the challenges and opportunities of implementing science- and risk-based manufacturing and decision-making approaches. The practice-based research emphasis of the PRST is on the development of *patient-focused strategies* to enable those involved in the manufacture of commercial drug products to meet the evolving international regulatory expectations, thus ensuring the *availability* of *high-quality* medicinal products.

Figure 1 below summarises the PRST journey from 2005 to present.

[1] https://prst.ie/

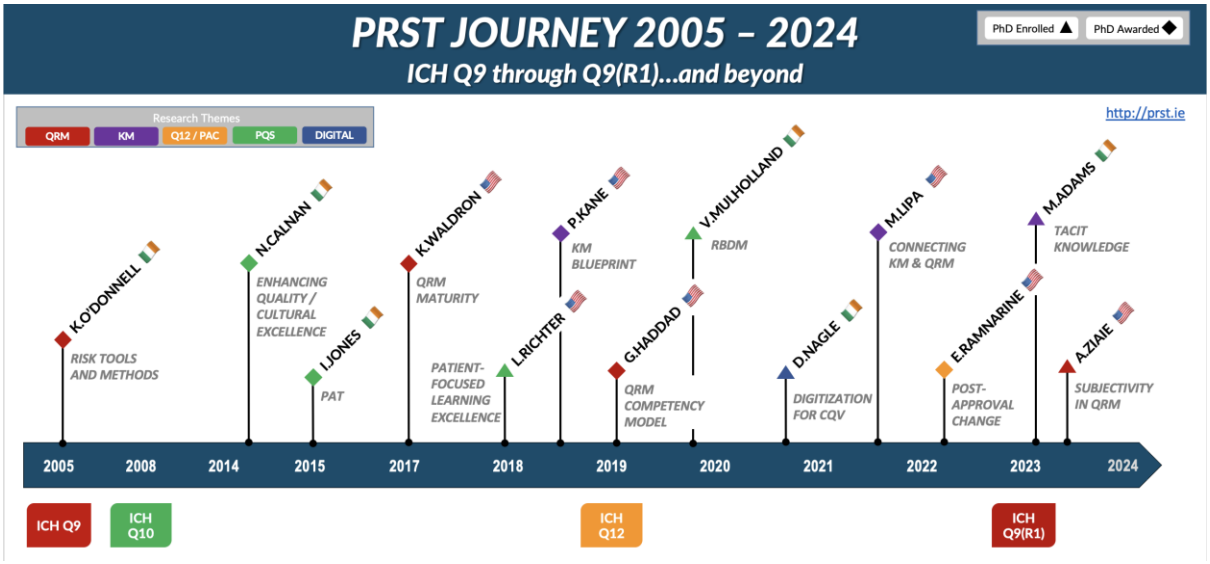

Figure 1 – PRST Journey from 2005 to Present

2. Evolving Regulatory and Industry Landscape

When the PRST was initially founded, the research focused exclusively on the application of quality risk management (QRM) and knowledge management (KM) principles and practices within the Good Manufacturing Practice (GMP) environment, and it proved to be an exciting time to be working in those areas. The FDA's *Pharmaceutical Quality for the 21st Century Initiative – A Risk-based Approach* initiative had been launched just a few years earlier by Dr Janet Woodcock, the then-director of the Centre for Drug Evaluation and Research (CDER) at the FDA, and ICH Q9 *Quality Risk Management* (1), was about to be finalised. There was a lot of momentum building across the industry and within regulatory agencies regarding risk; everyone seemed to be talking about quality risk management. A few years later, in June 2008, ICH Q10 *Pharmaceutical Quality System* (2), was published, positioning QRM and KM firmly at the centre of a modern pharmaceutical quality system (PQS). ICH Q10 presented QRM and KM as 'enablers' of the pharmaceutical quality system, where they would provide "*the means for science and risk-based decisions related to product quality*." During those same years, new concepts around the use of Process Analytical Technology (PAT) and Quality by Design (QbD) principles were also promoted, having been facilitated by the publication of the FDA's PAT guidance in 2004 (3) and ICH's *Pharmaceutical Development* guideline, ICH Q8(R2), in November 2008 (4). Everything seemed to be moving into place to support the new quality paradigm.

In response, the industry and its regulators launched a great many initiatives locally, regionally and internationally. The International Society for Pharmaceutical Engineering (ISPE) and the Parenteral Drug Association (PDA), for example, developed a range of papers, guides and technical reports that emphasised risk-based approaches, and, to a lesser extent, knowledge management. Furthermore, there was a vast number of conferences, seminars and training events to support these guides and reports. In the EU, the GMP guidelines were updated in 2008, to reflect risk-based approaches and embed QRM concepts across several areas, including validation, supplier oversight, deviation handling, quality defect management, advanced therapies and sterile product manufacturing. The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was also very active in this space over many years. In 2012, for example, PIC/S published a detailed methodology for risk-based GMP inspection

planning (5), and since 2010, it has provided QRM training to large numbers of GMP inspectors on the application and inspection of risk-based principles in many areas of GMP. The World Health Organisation (WHO) also developed a very comprehensive QRM guidance in 2010 and 2011 that has proven to be very useful (6).

However, while the paradigm shift proposed by ICH Q8/Q9/Q10 may have driven transformational changes in how the pharmaceutical industry and its regulators work within a GMP context, two main issues remain unresolved. These relate to the persistent problem of ***drug shortage*****s**, which is now a concern on a global scale, and the proliferation of ***quality defects and recalls*** of medicinal products manufactured using qualified equipment, validated manufacturing processes and trained staff. The increasing complexities affecting the landscape within which the biopharmaceutical industry operates have led to a characterisation of the *"wicked problem of ongoing drug shortages, quality defects, products recalls and a lack of innovation"* (7). This so called 'wicked problem'[2] presents a risk to patients reliably receiving every dose they need, every day. In identifying the underlying reasons for these drug shortages, the 2019 FDA report *Drug Shortages: Root Causes and Potential Solutions* (8) highlighted that 62% of drugs that went into shortage between 2013 and 2017 were associated with manufacturing or product quality problems. There is clearly more work still to do in the management of medicinal product risk!

Moving forward, the revision of ICH Q9 in 2023 to ICH Q9(R1) (9) has the potential to play a significant part in shaping future practices to address the above areas of concern. The ICH Q9 (R1) guideline, together with its associated training materials, provides guidance in numerous areas that were considered under-developed in relation to QRM practice, and it emphasises the crucial role of knowledge management in managing risk. This is a very welcome development.

3. The Work of the Pharmaceutical Regulatory Science Team

In parallel to the evolving regulatory landscape and in support of the paradigm shift, the PRST's body of work and influence has grown over the last 20 years, emerging from the doctoral research undertaken by its members. Figure 2 below illustrates a summary of this regulatory science research, with significant outputs and some of the key industry and regulatory collaboration activities highlighted.

[2] ***Wicked Problem****: A problem which is highly resistant to solutions, which are highly complex and cannot be well-defined, do not have easily defined solutions, and cannot be solved by any one group of people. (Rittel and Webber, 1973)*

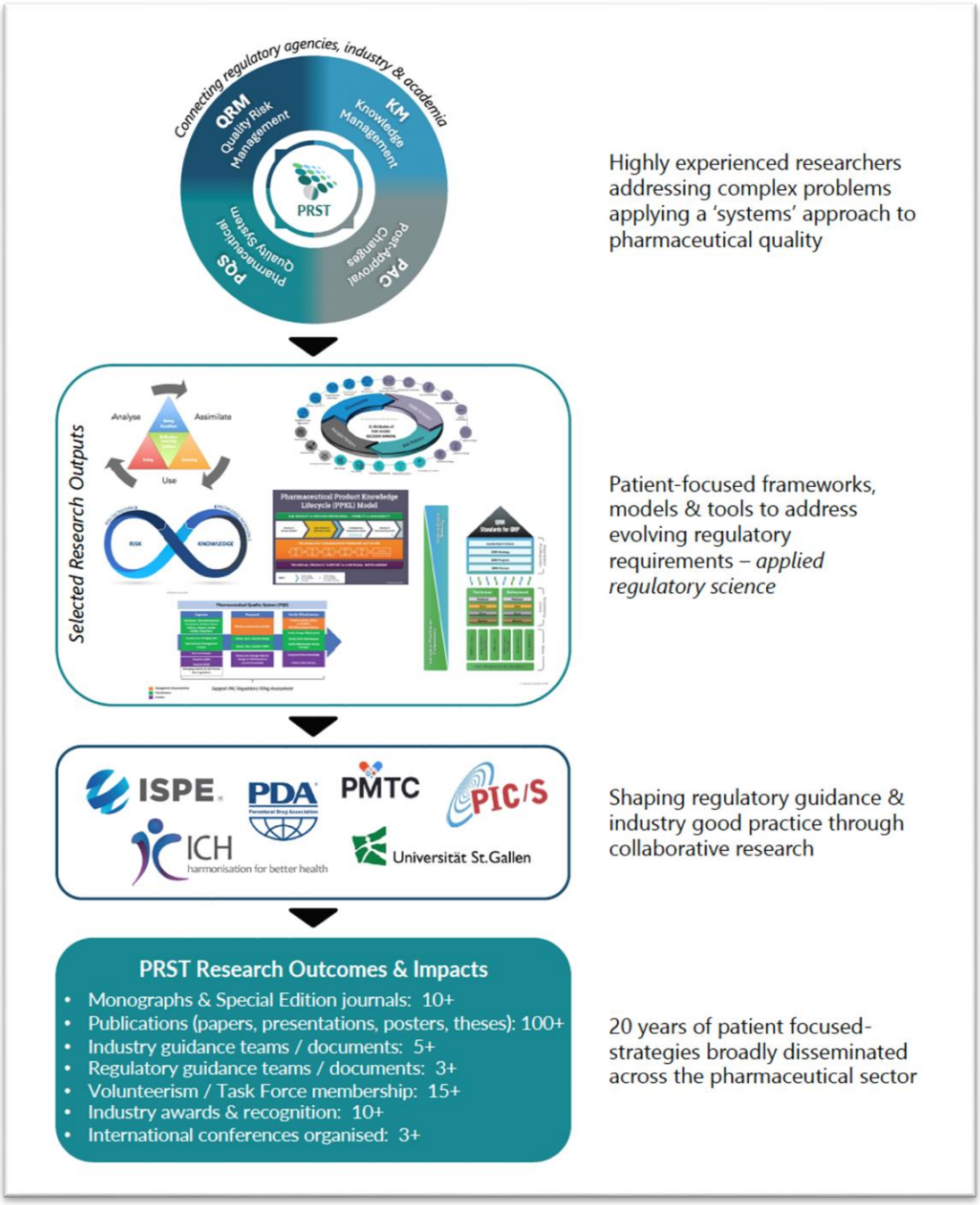

Figure 2 – The Work of the Pharmaceutical Regulatory Science Team

Further details of the research completed by each team member can be found in their PhD thesis documents, of which titles and years are presented in Table I.

Table I – PhD Research Completed by PRST Members 2008-2022

PhD Graduate	Thesis Title	Year Published
Kevin O'Donnell	The development of a Quality Risk Management Solution designed to facilitate compliance with the EU risk-based Qualification, Validation & Change Control GMP Requirements	2008
Nuala Calnan	Protecting the Patient - Enhancing the Quality of Pharmaceutical Products	2015
Ian Jones	The adaptation and integration of Imaging Technologies for use in pharmaceutical manufacturing	2015
Kelly Waldron	Managing Risk to the Patient, Recoding Quality Risk Management for the Pharmaceutical and Biopharmaceutical Industries	2018
Paige Kane	A Blueprint for Knowledge Management in the Biopharmaceutical Sector	2019
Ghada Haddad	Development of a competency frame for QRM	2019
Martin Lipa	Unlocking Knowledge to Benefit the Patient – How connecting KM and QRM can Strengthen Science and Risk Based Decision Making	2021
Emma Ramnarine	Solving the continual improvement and innovation challenge - How an Effective Pharmaceutical Quality System (PQS) & Risk-Based Approach can Transform Post-Approval Change (PAC) Management	2022

Each of these practice-based researchers continue to engage in valuable scholarly work, in particular supporting the current cohort of PRST PhD candidates, whose ongoing research topics are presented in Table II:

Table II – Ongoing PhD Research by Current PRST Members

Researcher	Research Working Title
Lorraine Richter	Enhancing Organisational Performance through Patient-Focused Learning Excellence in the Biopharmaceutical Industry
Valerie Mulholland	Effective Risk Based Decision Making in Quality Risk Management
Donnacha Nagle	Exploring Digitalisation in Pharmaceutical Manufacturing
Ann Ryan	Getting to the Root of Human Error in Biopharmaceutical Manufacturing Exploring Training, Human Factors and Ergonomics
Amin Ziaie	Exploring possible approaches to decoding subjectivity in Quality Risk Management

4. The Birth of a Journal

Over the past two decades, PRST members have disseminated their research outputs by presenting at numerous global conferences and publishing in key industry journals. Figure 3 below illustrates some of these publication platforms where PRST work has been presented.

Figure 3 – Publication Platforms where PRST Research has been Disseminated

More recently, driven by the desire to have a positive impact on the persistent global problem of drug shortages, the PRST has sought avenues to publish its work in open access publications. During 2018 to 2022, it published four monographs on its work, which are available via the TU Dublin research repository Arrow[3].

While publishing monographs proved to be a useful way to disseminate its work, in seeking a more flexible publication avenue the PRST was fortunate to be invited to publish special editions of the Technological University Dublin (TU Dublin) online journal *Level3*.

Level3[4] is an occasional online journal, devised in 2003 as a means of capturing and disseminating the variety and quality of research and innovatory practices within the DIT, now TU Dublin. Since its inauguration, over 20 issues of *Level3* have been published and its reach has extended internationally, beyond the confines of academia. It publishes on issues arising from general calls and on special issues related to industry-related research as well as providing academic commentary on significant contemporary issues.

Under the expert mentoring and guidance of our esteemed colleague Dr Anne Murphy, the PRST navigated the path of curating, editing and publishing online four special editions of *Level3*. These issues are as follows:

[3] https://arrow.tudublin.ie/
[4] https://arrow.tudublin.ie/level3/

- Volume 19, Issue 1 (2023), entitled: *ICH Q9(R1): The Next Frontier* (10)
- Volume 17, Issue 2 (2022), entitled: *Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape – Enabled Technology Transfer* (11)
- Volume 16, Issues 1 (2021) & Issue 2 (2022), entitled: *Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape – Linking Data, Analytics, Knowledge and Risk (Parts 1 and 2)* (12, 13)
- Volume 15, Issue 2 (2020), entitled: *Pharmaceutical Regulatory Science Matters* (14)

This experience was useful in preparing for the launch of the authors' new *Journal of Applied Pharmaceutical Regulatory Science (JAPRS)*, which will serve as a vehicle to aggregate the research of the PRST and other relevant global Applied Pharmaceutical Regulatory Science work, affording maximum opportunity for reach and impact for all key stakeholders.

In tandem with the inaugural edition of JAPRS where the work of the *One Voice of Quality (1VQ)* will be showcased, are two exciting initiatives which will come to fruition in May 2024. These will provide rich content for the second issue of the journal in the summer of 2024.

1. *Quality Business Leadership Summit, 1st May 202*4, TU Dublin Grangegorman. At this event we will bring together senior global leaders, from Academia, Industry and Regulatory organisations to explore the critical role of Quality Business Leadership in really driving innovation and continual improvement of the Pharmaceutical Quality System.

2. PRST member Dr Marty Lipa has been awarded a *Fulbright Specialist Award* to visit Ireland in May 2024, to undertake a project entitled: *Addressing the challenge of drug shortages by developing a curriculum designed to rethink global quality risk management practices by linking knowledge and risk*.

We look forward to launching the *Journal of Applied Pharmaceutical Regulatory Science* and are confident that readers will continue to learn from the new knowledge it will disseminate. We are hopeful that the dialogue and understanding it seeks to foster will enable us together to realise Janet Woodcock's vision for the benefit of patients globally.

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Dublin, Ireland
April 2024

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