Level 3

Volume 15 | Issue 2 Article 2

2020

Foreword to the Special Issue, December 2020 'Pharmaceutical Regulatory Science Matters'

LEVEL 3
A Technological University Dublin
journal of research and innovation

Special Issue

December 2020

Pharmaceutical Regulatory Science Matters

from the

Pharmaceutical Regulatory Science Team (PRST)

School of Chemistry and Pharmaceutical Science
Technological University Dublin

Foreword

The Pharmaceutical Regulatory Science Team (PRST) (www.prst.ie), in Technological University Dublin, was founded in 2005 in response to the drive for a paradigm shift in quality from the international regulatory community. PRST actively engages with global pharmaceutical industry and regulators to address the challenges and opportunities of implementing Science and Risk-based decision-making and manufacturing approaches. Since it's inception, the PRST has continued to progress research on quality risk management (QRM), knowledge management(KM), operational excellence(OpEx), post-approval change management (PAC, and PAC 1VQ), quality metrics and related topics covered by ICH Quality Guidelines.

Level3, an occasional on-line journal, was devised in 2003 as a means of capturing and disseminating online the variety and quality of research and innovatory educational practices within the Dublin Institute of Technology (DIT), now the Technological University Dublin. This special edition of *Level3* on *'Pharmaceutical Regulatory Science Matters'*, comprises of research papers based on the work of the PRST and the School of Pharmaceutical Science's *MSc in Pharmaceutical Validation Technology* and *MSc in Pharmaceutical Quality Assurance students*. Never before was the importance of the regulation of medicines more prominent than the year in which this research was carried out, 2020, as the world struggled to cope with the global pandemic of Covid19, and the race to find a vaccine.

The edition opens with research articles from PhD research candidates, focusing on KM, QRM, regulation of evolving therapeutics, and early academic research. This is followed by research articles from our MSc dissertation students, which stradle the pharmaceutical product lifecycle, starting first with development, then looking at technical transfer into the commercial phase, which is then explored through the lens of the PQS and auditing, before ending with the perspective of the patient. The final section of the monograph presents research articles from PRST members and collaborate work with global colleagues. In particular we are delighted to be able to present the work of the *'1 Voice of Quality'* 1VQ team (www.prst.ie/1VQ), and we are grateful for permission from IVT to reproduce these and other papers, previously published in their Journal of Validation Technology, in this edition of *Level3*.

Finally, I would like to take the opportuity to give a special thanks to all of our Peer Reviewers.

On behalf of all the authors and the editorial team, we hope you enjoy this special edition of *Level3*

Professor Anne Greene *December 2020*

CONTENTS

PART 2: Research articles from MSc cohorts on the Pharmaceutical Validation Technology (PVT) and Pharmaceutical Quality Assurance (PQA) programmes, TU Dublin

7. Eimear O'Reilly, TUDublin, **Elaine Harris,** TUDublin & PRST

From idea to therapeutic – Is there a role for developing a regulatory pathway tool for early stage research?
PEER REVIEWED

8. **Layth Ujam**, TUDublin

The 5C Framework and Maturity Assessment: A New Approach to Technology Transfer in Biopharmaceutical Contract Manufacturing
PEER REVIEWED

9. Susan McDonagh, TU Dublin

Exploring the Advantages of Implementing ICH Q12
PEER REVIEWED

10. Magan Hannon, TU Dublin

The Challenges of Remote Auditing Faced by the Pharmaceutical Industry
PEER REVIEWED

11. **Helena Scully**, TUDublin, **Fiona O'Sullivan,** TUDublin

Development of the Self Inspection Programme to assist demonstrating PQS effectiveness
PEER REVIEWED

12. Maria Makarevich, TUDubin: **Valerie Mulholland*** GMP Services, TUDublin & PRST

Introducing SI-PEA – a risk-based tool to measure the effectiveness of your self-inspection programme
PEER REVIEWED

13. Maria Gormley, TUDublin

Assessing if patients in would benefit from Electronic Patient Information Leaflets (ePILs)
PEER REVIEWED

PART 3: Research articles from PRST members & collaborative work with global colleagues

14. **Paige Kane***PRST; **Anne Greene,** TUDubin & PRST

Opportunities to enrich collaboration and best practice sharing in the COVID work environment

15.: **Umit Kartoglu**, Extensio et Progressio; **Kevin O'Donnell*** HPRA & PRST; **James Vesper**, ValSource LLC

COVID-19 AND THE NEED FOR ROBUST RISK CONTROL STRATEGIES – CAN ICH-Q9 HELP?

This paper was previously published in the Journal of Validation Technology and the Journal of GXP Compliance, and is published by TU Dublin with the permission of the editors of the respective journals. (www.ivtnetwork.com)

16. **Kevin O'Donnell*** HPRA & PRST; **Deirdre Tobin** MSD; **Stephanie Butler**, Jazz Pharmaceuticals; **Ghada Haddad**, MSD & PRST; **Donal Kelleher**, MSD

Understanding the Concept of Formality in Quality Risk Management

This paper was previously published in the Journal of Validation Technology and the Journal of GXP Compliance, and is published by TU Dublin with the permission of the editors of the respective journals. (www.ivtnetwork.com)

17. **Industry One-Voice-of-Quality (1VQ) www.prst.ie/1VQ**

Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches*: Shelf-Life Extensions for Pharmaceutical Products*

This 1VQ paper was previously published in the Journal of Validation Technology and the Journal of GXP Compliance, and is published by TU Dublin with the permission of the editors of the respective journals. (www.ivtnetwork.com)

18. Industry One-Voice-of-Quality (1VQ) www.prst.ie/1VQ

Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches: *Changes to Analytical Equipment/Instrumentation that are Deemed Equivalent*

This 1VQ paper was previously published in the Journal of Validation Technology and the Journal of GXP Compliance, and is published by TU Dublin with the permission of the editors of the respective journals. (www.ivtnetwork.com)

19. **Joe Brady**, TUDublin & PRST

24 Things I've Learned in 24 Years about Technology Transfer

20. Marty Lipa*,TUDublin & PRST. **Paige Kane,** PRST. **Anne Greene**, TUDublin & PRST

Simple Practices to Facilitate the Flow of Valuable Tacit Knowledge during Biopharmaceutical Technology Transfer: **A Case Study**