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

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Special Issue

December 2020

Pharmaceutical Regulatory Science Matters

from the

Pharmaceutical Regulatory Science Team (PRST)

School of Chemistry and Pharmaceutical Science
Technological University Dublin



Pharmaceutical
REGULATORY SCIENCE
Team



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 its 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 innovative 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 straddle 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 opportunity 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

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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)

2. Marty Lipa*, MSD, TUDublin & PRST: **Kevin O'Donnell**, HPRA & PRST: **Anne Greene**, TUDublin & PRST

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