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Linking Data, Analytics, Knowledge and Risk*

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“Connecting the dots to a Digital Future, Transitioning from Data to Informed Decisions”

Marcus O'Mahony

*Pharmaceutical Manufacturing Technology Centre (PMTc), Bernal Institute, University of Limerick, Ireland,
marcus.omahony@ul.ie*

Anne Greene

Pharmaceutical Regulatory Science Team (PRST), Convene, TU Dublin, Ireland, anne.greene@tudublin.ie

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FOREWORD

Connecting the Dots to a Digital Future: *Transitioning from Data to Informed Decisions*

Marcus O'Mahony¹ & Anne Greene²

¹ Pharmaceutical Manufacturing Technology Centre, Bernal Institute, University of Limerick, Ireland

² PRST, Convene, TU Dublin, Ireland

The origins of this collaborative Special Issue between the PMTC at the University of Limerick, and the PRST group at Technical University Dublin, began with the development of the PMTC good practice guide to data analytics which was launched in late 2020. The guide was reviewed with the regulators and the PRST group, and through that effort, some regulatory concerns and opportunities relating to the expanded use of data analytics across the pharmaceutical manufacturing sector were brought to light. In February 2021 the PMTC Data Analytics Community of Practice for Pharma (DACoPP) was established. This community brings together industry, academics, and regulators with the aim of increasing the adoption of data analytics tools and techniques in the pharma manufacturing sector, and in doing so, supporting the sector in Ireland through its digital transformation efforts.

Through the delivery of the good practice guide, and with the continued conversations happening within the DACoPP, it became clear that a new and important interface around knowledge 'generation-integration' was emerging. On one side, the ever-expanding volume and diversity of data and new digital technologies requires increasing amount of computation, as well as mathematical and statistical analysis for new knowledge generation. And on the other side, medicines being

manufactured in increasingly data rich environments require good knowledge management practices to be well-integrated in order to best manage risk during product realisation, control and process improvement. Connecting the dots (or bits!) between data and informed decisions is a critical part of the digital transformation journey for the pharmaceutical manufacturing sector.

The purpose of this Special Issue is to touch on the digital transformation happening right now across the pharmaceutical manufacturing landscape, and to begin to look at the knowledge generation-integration interface between data and analytics on one side, and knowledge and risk management practices on the other.

In this Special Issue we bring together examples of advanced data and digital technology use. We also bring the regulatory voice to the fore, making the case for more informed decision making. Data analytics should support better quality risk management, and this in turn should support better outcomes for both business and patient.

This Special Issue begins with an academic section which seeks an understanding of risk-based decision making in the context of Quality Risk Management and explores the journey from data to insights. The Special Issue then progresses to present a series of industry-developed case studies which present examples of data analytics solutions being deployed across the sector.

The focus then shifts to how data transformation can be regulated, and can contribute to ensuring quality to deliver better patient outcomes. The Special Edition concludes with an FDA-funded research programme which described an ongoing study into developing a data-based approach to site quality risk identification and assessment.

The authors of this Foreword would like to sincerely thank all those who brought forward case studies and contributed content to this Special Issue.

On behalf of all the authors herein and the editorial team, we hope you enjoy this Special Issue and that it will encourage further dialogue and exploration of the interaction between Data, Analytics, Knowledge and Risk.

Professor Anne Greene

PRST, Convene, TU Dublin

Dr Marcus O' Mahony

PMTC, University of Limerick