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Benchmarking the Pharmaceutical Industry: A Briefing on an Irish Research Study

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Benchmarking the Industry
A briefing on the Research Study

ISPE Quality Risk Management Conference April 11th – 12th 2011 Frankfurt, Germany





Profile of DIT

- Dublin Institute of Technology (DIT) is a comprehensive, doctoralawarding institution, combining the academic excellence of a traditional university with professional, career oriented learning
- DIT is committed to excellence in research.
- Led by Professor Ellen Hazelkorn, DIT's research strategy is built on the development of research excellence in 6 key areas:
 - the Creative Arts and Media, Food & Health Sciences, Environmental Sustainability, ICT, Business and Social Economic Development and New Materials and Technologies.
- The QS World University Rankings lists DIT among the top 3% of the world's universities.

Somewhere, something incredible is waiting to be known - Dr Carl Sagan







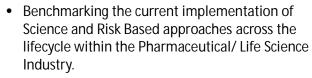
PhD Research Study

Purpose:

The Development of an <u>effective</u> Science and Risk Based Methodology for the Validation of Manufacturing Processes used in the Production of Human Drug and Biological Products, based on the recent ASTM International E2500-07 Standard and lean principles.



Questionnaire



- The study will also examine the current regulatory environment and seek to establish the regulatory status of Science & Risk based applications within the Industry.
- It is planned that the results of this study will be published in a peer reviewed journal in 2011. Thank you for your participation











Instructions

- Review the Information Sheet provided
- Sign and Date the Consent Form to receive your numbered Questionnaire
- Complete the 4 page Questionnaire provided and return to Nuala Calnan in person at any time during the conference.

Thank You