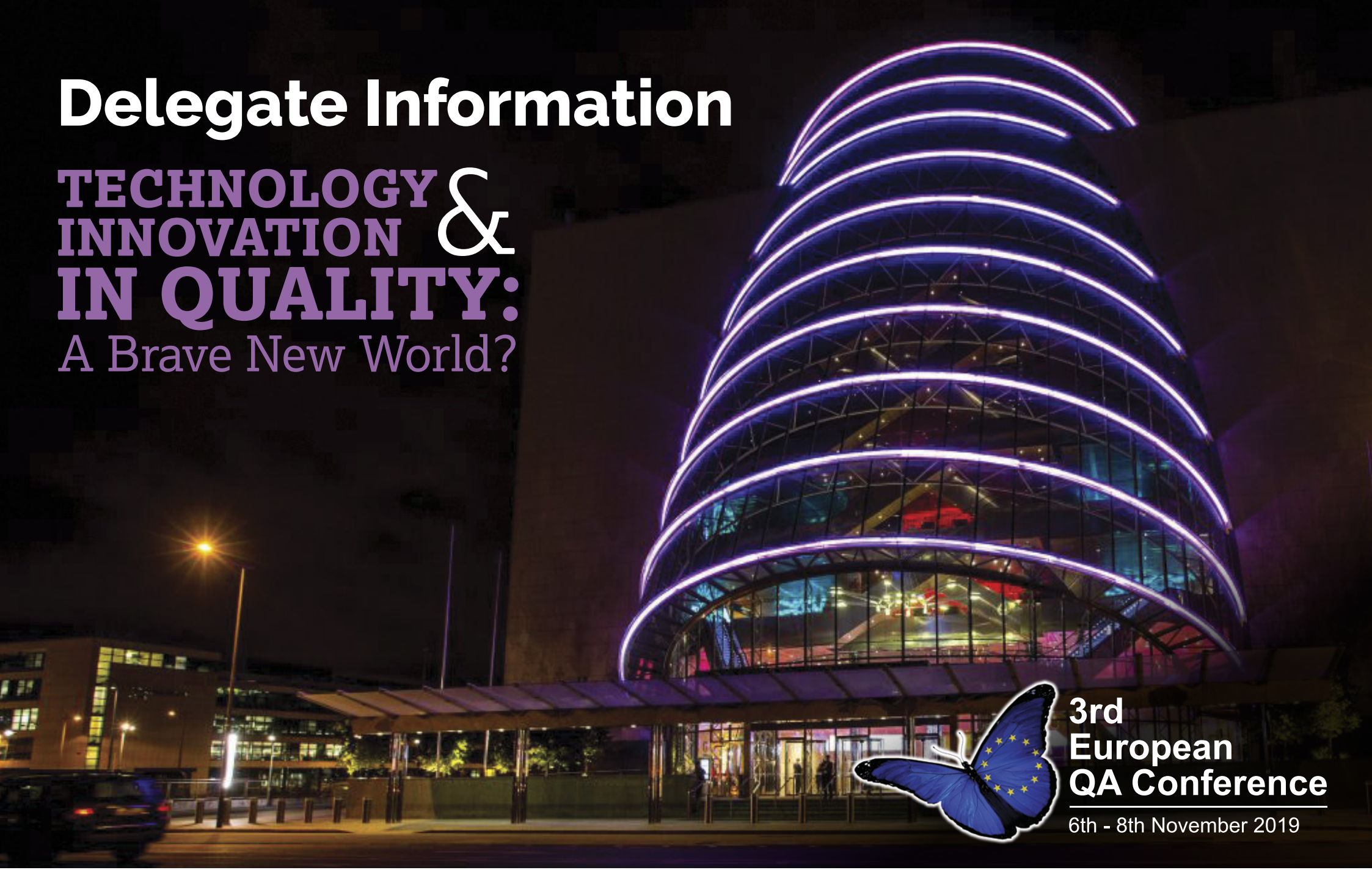
Delegate Information

TECHNOLOGY & INNOVATION IN QUALITY:

A Brave New World?



3rd European QA Conference

6th - 8th November 2019

RQA

GQMA GERMAN QUALITY MANAGEMENT ASSOCIATION E.V.

SOFAQ FRENCH QUALITY ASSURANCE SOCIETY

The 3rd
European QA Conference

TECHNOLOGY & INNOVATION IN QUALITY:
A Brave New World?

2019 sees the return of the highly-popular European QA Conference, previously held in 2013 and 2016. The third conference is hosted by RQA, GQMA and SOFAQ with the support of other European Associations.

Venue: The Convention Centre Dublin (The CCD)

Dates: 6th–8th November 2019.

This will be Europe's largest quality assurance event and will consist of plenary, parallel, discussion and workshop sessions together with a large exhibition and poster area.

We are anticipating around 400 delegates to attend.

Reasons to attend:

- A truly European conference, this year's Programme Committee was made up of members from RQA, GQMA and SOFAQ as well as representation from Spain (SEGCIB) and The Netherlands (DARQA)
- Regulators will be in attendance from all over Europe, speaking to delegates on a variety of topics and being involved in the popular 'Regulator's Roundtable' on Friday morning
- Speakers will also be drawn from across Europe to provide delegates with a wide and varied experience
- Streams will cover Academia, Animal Health, Computing, GCP, GDP, GLP, GMP, Medical Devices and PV
- The conference will be a great opportunity for networking with like-minded colleagues – from breaks and interactive sessions, to QA clinics and drinks receptions, there will be ample opportunity to catch up with previous acquaintances and make new ones
- A large exhibition area will allow delegates to network with up to 40 suppliers and recruitment agencies
- Dublin is the number one destination in Ireland A city with history, charm, sights, museums, galleries, theatres, shops, pubs, restaurants and an abundance of character.

Welcome to Dublin

The Convention Centre Dublin

The CCD was developed to provide a world-class conference venue in the heart of Ireland's capital city. Located just 15 minutes from the airport in Dublin's Docklands, the finance and technology hub of the city.

Since The CCD opened in September 2010, it has hosted over 1,500 events.

The CCD has won 40 industry awards, and continues to position Ireland on the world stage for international conferences, congresses and events. The venue is truly world-class in every sense, from the quality of the facility, through to every aspect of their service. It offers conference and event organisers, as well as conference delegates, an unrivalled event experience.

The CCD is a truly iconic building, inside and out. Learn more about the building's design and construction, as well as the architectural vision behind it by visiting its website **www.theccd.ie**

Things to see and do

As one of Europe's most popular destinations, Dublin offers visitors an endless amount of things to see and do, many of which are within walking distance or a short tram ride from The CCD.

No journey to Dublin is complete without visiting the famous Temple Bar area. Here you can grab a bite to eat, walk the famous cobbled streets, soak up the lively atmosphere in one of the many typical Irish pubs, and listen to some of the best live traditional music in the city.

With so much to do in and around Dublin, you may wonder when you will get time to sleep. But when that time does come, there are over 18,500 hotel rooms with options to suit every budget.

To familiarise yourself with the city, why not start off with a tour of the city? There are a selection of tours available, from guided walking tours and hop-on/hop-off double-decker bus tours to the Viking Splash Tour that takes you over land and sea in an amphibious vehicle.

Most visits to Dublin will probably involve a trip to the world famous Guinness Storehouse, home of the traditional pint of Guinness. Here you can take the visitor experience tour and enjoy a pint of the 'black stuff' in the spectacular surroundings of the Gravity Bar.

Pricing

1 Day
Member* **£522.00**
Non-member **£737.00**
Dinner dance tickets **£75.00** each

2½ Days – Early bird full delegate
Member* **£720.00** Early bird pricing is available until 2nd September 2019
Non-member **£938.00**
Gala dinner dance ticket **£FREE!** (Save £75.00! Additional dinner dance tickets can be purchased for guests at £75.00 each)
RQA Pre-conference training **10% DISCOUNT** When booking at the same time as the conference using code: **PRECON**

2 Day
Member* **£654.00**
Non-member **£871.00**
Dinner dance tickets **£75.00** each
RQA Pre-conference training **10% DISCOUNT** When booking at the same time as the conference using code: **PRECON**

Prices shown do not include Irish VAT at 23%.

* The member rate is available for members of RQA. Members of GQMA, SOFAQ, DARQA and SEGCIB can also use the members rate using the code supplied by their association.

Wednesday 6th November 2019

Morning sessions 1 and 2 – Plenary

The 3rd European QA Conference

Facts and Figures

Nearly 60 different presentations, workshops or clinics covering Academia, Animal Health, Computing, GCP, GDP, GLP, GMP, Medical Devices and PV.

Over 50 speakers from all over the world

Up to 40 exhibitors

The Conference App will give real time access to presentations, as well as enabling all participants to ask questions and answer polls set by the presenters.

Session 1

Technology and Innovation in Quality: A Brave New World?

Chairs: Kath Williams (RQA) / Steffen Koenig (GQMA) / Laurent Bouillot (SOFAQ)

09.20 Opening address

Kath Williams/Steffen Koenig/ Laurent Bouillot
European Association Chairs

09.30 Keynote Address

Dr Phil Hammond
Broadcaster

Phil Hammond is a doctor, journalist, broadcaster, campaigner and comedian. He qualified as a GP in 1991 and currently works in a specialist NHS centre for children and adolescents with chronic fatigue syndrome/ME. Phil has been Private Eye's medical correspondent since 1992, campaigning for patient empowerment, open data in healthcare and for the NHS to be honest and transparent about the harm it causes as well as the good it does.

In 2012, he was shortlisted with Andrew Bousfield for the Martha Gellhorn Prize for Investigative Journalism for a Private Eye Special Report about the shocking treatment of NHS Whistleblowers. Phil has also won awards for broadcasting, popular health journalism, comedy and teaching.

10.30 Refreshment break

Session 2

The Rise of the Machines

Chair: Barney Horne (RQA)

11.00 AI & Machine Learning in Drug Discovery

Lindsay Edwards and Bill Byrom
GSK / CRF Health

- Artificial Intelligence
- Machine Learning
- Automation
- Wearables.

11.45 Applying Advanced Analytics to Quality Assurance

Timothé Ménard
F. Hoffmann – La Roche Ltd

Introduction – key concepts and terminologies (machine learning, AI, etc.)

- Why leveraging on advanced analytics in Quality Assurance (QA)?
- Use cases of advanced analytics in QA
- Capabilities required for advanced analytics in QA
- Foster a "data analytics culture" in QA
- The future of Quality Assurance.

12.30 Lunch

Wednesday 6th November 2019

Afternoon session 3 – Streams

Session 3

Animal Health

Chair: Sven Buckingham (RQA)

13.30 TBC

14.00 TBC

14.30 TBC

15.00 Refreshment break

Session 3

Academia

Chair: Christine Toneatti (SOFAQ)
Tracy Gilbert (RQA)

13.30 Quality Criteria for Repositories Hosting Clinical Trial Data

Rita Banzi
Mario Negri Institute Milan

- Discuss the role of data repositories in the effective and safe sharing of individual-participant data from clinical studies
- Review the efforts to standardise data sharing practices through data repositories.

14.00 Enhancing High-Quality Data Management Services in European Non-Commercial Clinical Trials

Christine Toneatti
ECRIN

- A review of the ECRIN Data Centre Certification Programme
- How the model demonstrates its effectiveness based on the broad acceptance of the ECRIN standards
- How the model is expanding into Asia.

14.30 Archiving of Electronic Data in Clinical Trials

Alan Yeomans
PCG Solutions AB

- EMA's discussions surrounding technical issues concerning the use of computerised systems for clinical research
- The decision to collaborate on a position paper describing industry best practices and recommendations on several topics.

15.00 Refreshment break

Session 3

PV/GCP

Chair: Glene Sandom (RQA)

13.30 PASS/PAES – Is It Just About Gathering Safety and Efficacy Data?

Wendy Koç
Gilead

- Management and audit of PASS/PAES – past and present.

14.00 GCP/GMP Aspect of the PSMF

Michael Bean
Johnson & Johnson

- Interfaces between PSMF and GCP/GMP including audits, vendors and studies activities.

14.30 Risk Minimisation

Brigette Keller-Stanislavski
PEI

- TBC

15.00 Refreshment break

Session 3

Medical Devices

Chair: Colette McIntyre (RQA)

13.30 Quality in Product Innovations for Start-Ups, SME, and Incumbent Medical Device Manufacturers Through the New EU Medical Device Regulation

Dr Max Singh
TUEV SUED Product Service GmbH

- Overview of the EU MDR
- Important Timelines & Changes
- Consequences for different Types of Medical Device Manufacturers.

14.00 TBC

14.30 Cybersecurity in Medical Devices

Dr. Peter Graham
HeartSine

- TBC

15.00 Refreshment break

Wednesday 6th November 2019

Afternoon session 4 – Streams

Session 4

Animal Health

Chair: Nuria Puigoriol (SEGCIB)

15.30 Auditing Research Animal Facilities

Helena Paradell
Zoetis

- Discussion of the main concepts and tools when evaluating research animal facilities, including animal care and welfare practices.

16.00 Animal Health QA Clinic

Janice Sarasola
Ondax Scientific

- This interactive clinic session will explore the challenges for the Quality Assurance professional when auditing Animal Health Clinical Trials using Electronic Data Capture (EDC) systems.

17.15 Meet the Delegates Drinks Reception

Session 4

GMP/GDP

Chair: Rose Buot/Laurent Bouillot (SOFAQ)

15.30 Annex 1: Vision Global

Mr Jean-Francois Beck
GoTrain

- Global overview and impact of revised Annex 1
- Where and how it is applied?

16.00 Planning and Implementation of EU GMP Annex 1 Update

Jennifer Hynes
Benchmark Vaccines Limited

- Real life examples of the challenges the updates to EU GMP Annex 1 has presented to a Veterinary Vaccine Manufacturing facility.

16.30 GDP From a Transportation Company Perspective

Dr Valler de Quikstate

- TBC

17.15 Meet the Delegates Drinks Reception

Session 4

PV

Chair: Allison Jack (RQA)

15.30 An MHRA Perspective on Automation, Machine Learning & Artificial Intelligence

Phil Tregunno
MHRA

- An overview of the MHRA's perspective on implementation of novel Pharmcovigilance systems.

16.00 Brexit PV Challenges

Liz Hancox
GSK

- Brexit challenges
- Emerging markets challenges.

16.30 Inspection of PV IT Systems

Diane Hallé
ANSM

- How are PV IT systems inspected?
- What documentation is required to be available for inspection?
- Examples of deficiencies in PV IT systems identified during PV inspections.

17.15 Meet the Delegates Drinks Reception

Session 4

Medical Devices

Chair: Markus Hahn (GQMA)

15.30 Use of Eye Tracking Technology in Usability Studies to Improve Device User Interface Design

Hannah Torney
HeartSine

- TBC

16.00 ISO 14155 Revision Update

Danielle Giroud
MD Clinicals

- A look at how to take ISO 14155 FDIS 2019 into account to ensure compliance when designing any clinical investigation
- Learn about such important strategy planning taking into account full compliance with ISO 14155 FDIS 2019.

16.30 TBC

17.15 Meet the Delegates Drinks Reception

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Thursday 7th November 2019

Morning sessions 1 and 2 – Streams

Session 1

GCP Renovation and Transformation

Chair: Kerstin Koenig (GQMA)

09.00 GCP Renovation – ICH E8 and ICH E6

Fergus Sweeney
EMA

- TBC

09:45 Clinical Quality-by-Design (QbD): Principles to Practice

Ann Meeker-O'Connell
IQVIA

- Discuss clinical QbD origins, concepts and application
- Review existing QbD resources from the Clinical Trials Transformation Initiative (CTTI)
- Discuss ongoing CTTI QbD Adoption project and planned products.

10.30 Refreshment break

Session 1

GLP

Chair: Catherine Liang (SOFAQ)

09.00 OECD Document on Test Item Management: What is New?

Thomas Lucotte
ANSM

- This presentation aims to underline the clarifications of the GLP principles brought by Document No. 19 and the expectations of the monitoring authorities.

09.30 Bridging the Gap between New (and Not so New) Technologies and the Regulations

Sara Rybak
Charles River

- New methodology, equipment, and products are being developed and used in regulated work, often ahead of regulatory guidelines
- One or two case studies will be discussed.

10.00 Digital Pathology, Quality Expectations and Regulatory Requirements to Ensure Data Quality and Data Integrity

Alain Piton
ALP Quality Systems

- Digital pathology and use of electronic data create a challenge to ensure the quality and reliability of data
- Appropriate dispositions to ensure GLP compliance and data integrity during the entire lifecycle of images and data are of paramount importance
- Regulatory viewpoint and the quality management expectations.

10.30 Refreshment break

Session 1

Computing/IT

Chair: Daniel Caparros (GQMA)

09.00 Self-Driving Cars Take Ethical Decisions – Let's Talk About AI in Healthcare

Ingo Baumann
Thescon GmbH

- Artificial Intelligence offers promising opportunities for the healthcare industry. But do unlimited possibilities come with unlimited risks? How can AI applications be controlled and validated?

09.30 Leveraging Knowledge Graphs, Data Linking and Semantic Technologies for Quality Assurance

Sören Auer
TIB Leibniz Information Center for Science and Technology

- Knowledge Graphs, Linked Data and Semantic Technologies are gaining increasingly traction in the industry.
- In particular, their value for data integrity, consistency, interoperability, provenance and traceability can hardly be underestimated.

10.00 Thinking Risk to Determine Strategy

Barry McManus
Empowerment Quality Engineering Ltd

- Risk Management can be inadequate and sometimes a liability in CSV projects. Taking security as a theme, this presentation will examine how to improve Risk effectiveness.

10.30 Refreshment break

Session 2

GCP Big Data – where do we go from here?

Chair: Salvador Ribas (SEGCIB)

11.00 TBC

11.30 Regulatory Perspective on Direct Data Capture by Trial Subjects and Their Social Media Use

Dr Torsten Stemmler
BfArM

- Data Safety
- Date Integrity
- Data Validity
- Data Privacy.

12.00 Auditing Real World Evidence (RWE)/Real World Data (RWD)

Mercedes Martinez
Eli Lilly and Company

- What to audit: risk assessment for RWE studies
- Skills of the RWE/RWD auditor
- How good is the data? Design, acquisition and control
- How robust are data analysis and interpretation?

12.30 Lunch break

Session 2

GLP

Chair: Jane Elliston (RQA)

11.00 GLP Workshop

Paul Davidson
Headway Quality Evolution

Lesley Graham
AstraZeneca

Mark Goodwin
GSK

…based on the following questions

- How do you audit an audit trail?
- Paper data or electronic?
- Do you know where to start?
- How much access do you have to systems?
- Do you know where to focus your attention?
- Where is the line between QA and QC?

12.30 Lunch break

Session 2

Computing/IT

Chair: Trev Simmons (RQA)

11.00 Blockchain and the Next Steps

Matt Jones
Digital Quality Associates

- Movements in the market
- Tokenisation – the big bang
- Fulfilling transactions
- Value drivers for disruption.

11.30 A Story About FIT EDDI and the COMET

Olga Stoll
Bayer

- Megatrends – The evolution of tomorrow
- Changing IT landscapes in the pharmaceutical industry
- Data integrity at the heart of regulatory authorities
- Is your IT audit approach fit for the future?
- How to overcome challenges and open up opportunities?

12.00 Computing/IT QA Clinic

Panel drawn from GQMA/RQA representatives

- Question and Answers for any questions delegates may have.

12.30 Lunch break

Thursday 7th November 2019

Afternoon sessions 3 and 4 – Streams

Session 3

GCP QMS beyond QA compliance

Chair: Angelika Tillmann (RQA)

13.30 eSource Direct Data Capture and eConsent

Rebecca Stanbrook / Melika Davis
Novartis

eSource – direct data capture

- What do we mean by eSource?
- How could it potentially be used?
- Sharing our experience with regulators.

eConsent

- What is the benefit for patients?
- Review some example use cases
- Sharing our experience with regulators.

14.00 Audit Trail Review During Audits – Practical Aspects

Aurelie Delaunay
Merck KGaA

- Audit trail review requirements
- Added values of audit trail review during audits
- Auditor review practical examples including main steps, potential challenges and outcome.

14.30 The Role of Technology in Streamlining Audits

Michael Baptist
Medpace

- Current trends in audits
- Leveraging technology and data anayltics
- Remote audits and virtual tours.

15.00 Refreshment break

Session 3

GLP

Chair: Marijke Steenvoorde (DARQA)

13.30 The Cloud

Hans de Raad
OpenNovations

- TBC

14:15 e-Archiving in the Cloud: Strengths and Limitations. Are We in Control?

Elisavet Kyriakou
Charles River

- History of archiving, from paper to e-records
- Roles and responsibilities of archive staff and/or IT
- e-Archiving strengths and limitations in the cloud
- Lessons learned in global organisation and attention points.

15.00 Refreshment break

Session 3

PV

Chair: Alain Piton (SOFAQ)

13.30 Outsourcing Pharmacovigilance Activities: How to Set It Right, a MAH Perspective

Alina Tudor
Norgine Pharmaceuticals

- Outsourcing PV: how and what to choose?
- Safety activities to be outsourced vs. vendors expertise
- Methods of oversight.

14.00 Challenges Faced in Working With Multiple Clients – a Service Provider's Perspective

Mark Banahan
IQVIA

- How to manage oversight of KPIs, Status reporting, Quality indicators, role technology and innovation.

14.30 Managing PV: How to Future Proof Your Organisation, With the Application of Technology and Innovation

Alison Sloane
IQVIA

- The Pharmacovigilance landscape – opportunities and solutions for tech enabled services and automation
- Automation today and tomorrow
- Key considerations in preparing for change
- How to maximise ROI.

15.00 Refreshment break

Session 4

GCP: Hot Topics

Chair: Angelika Tillmann (RQA)

15.30 Every Patient Counts: Evolving Models for Hybrid and Virtual Trials

Ben Quartley
Covance

- Trial virtualisation drivers and directions why it matters in a global context.
- Hybrid trials.
- Experience with virtual real world evidence trials.
- Value of partnership.

16.00 GCP QA Clinic

TBC

- Facilitated discussions of current GCP hot topics with the audience.

17.15 RQA AGM

19.00 Pre Dinner Dance Drinks Reception

19.30 Dinner Dance

Session 4

GLP

Chair: Uli Schepers (GQMA)

15.30 GLP Roundtable Discussion

Inspectors of different European GLP Monitoring Authorities

- A Q&A led by Uli Schepers with various European regulators.

17.15 RQA AGM

19.00 Pre Dinner Dance Drinks Reception

19.30 Dinner Dance

Session 4

PV

Chair: Louise Handy (RQA)

15.30 Collecting Safety Data from Commercial Activities

Manjit Virdee
GSK

- Types of commercial activities and their design (e.g. patient support programmes, interactive digital media, market research)
- Challenges of collecting safety data from commercial activities
- Value of data obtained.

15:55 Arab Pharmacovigilance Guidelines Overview

Jaber Jaber
Jordan Food & Drug Administration

- An overview about Arab Pharmacovigilance requirements.

15:55 PV QA Clinic

Raj Bhogal
GSK

Topics to include:

- Auditing third parties
- IDM
- IDM Vendors
- Regulatory inspections
- Using AI to assist in auditing.

17.15 RQA AGM

19.00 Pre Dinner Dance Drinks Reception

19.30 Dinner Dance

Friday 8th November 2019

Morning sessions 1 and 2 – Plenary

Session 1

GxP Expert Roundtable

Chair: Barney Horne (RQA)

9.15 **Future of QA in a changing world**

Carla Wandt (Roche), Monika Pietrek (Pietrek Associates), Ann Meeker-O'Connell (IQVIA) Deb Driscoll (MSD)

Panel Discussion.

- Where is Quality now and why we must change?
- New approaches for quality professionals
- Meeting the challenges of our rapidly changing environment.

10.15 Break

Session 2

Regulators Roundtable

Chairs: Kath Williams (RQA), Steffen Koenig (GQMA), Laurent Bouillot (SOFAQ)

10.45 **Regulators Roundtable**

Regulators from around Europe.

Close of Conference

12.00 **Technology and Innovation in Quality: A Brave New World?**

European Association Chairs

Pre-conference Training

The RQA is holding four pre-conference training events. These will all be held at the Gibson Hotel.

Courses

The Auditing Course, 4th – 5th November

Implementing Good Clinical Laboratory Practice, 4th – 5th November

A Masterclass in Pharmacovigilance Auditing, 4th – 5th November

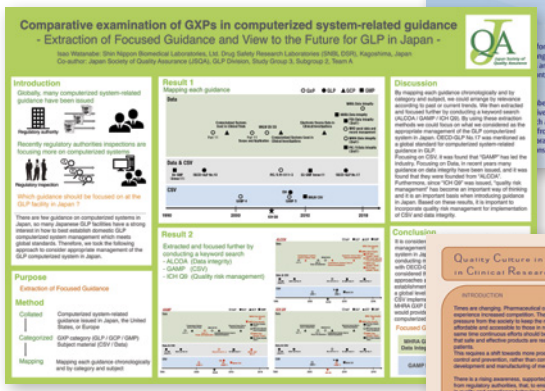
Seminar

Manageable Risk: Focusing on What Matters in Clinical Trials, 5th November

Full and two day delegates will receive 10% discount on fees when booking as a conference delegate at the same time, using the code: ***PRECON***

Call for Posters

Poster displays will showcase a wide range of subjects.



Posters will be displayed from Wednesday 6th to Friday 8th November 2019.

The Programme Committee will consider posters which address:

- Scientific and technical topics with a focus on quality
- The activities of national and international quality societies.

Posters will be selected based in innovation, topicality and applicability to the conference programme and delegates.

Please submit poster abstracts to: **conferences@therqa.com** by 2nd September 2019.

The Programme Committee will judge the posters while at the conference and the winner will receive a place at RQA's 2020 Annual Conference. We will also provide opportunity for an informal Q&A with delegates who wish to discuss your posters during the afternoon breaks.

Useful Contacts:

Conference bookings:
www.therqa.com/conferences/3rd-european-qa-conference

Conference queries:
conferences@therqa.com

+44 (0) 1473 221411

Pre-conference training bookings:
www.therqa.com/learning/events

Pre-conference training queries:
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Accommodation Bookings:
www.successfuleventslive.co.uk/3rdEuropean2019QAConference

The CCD:
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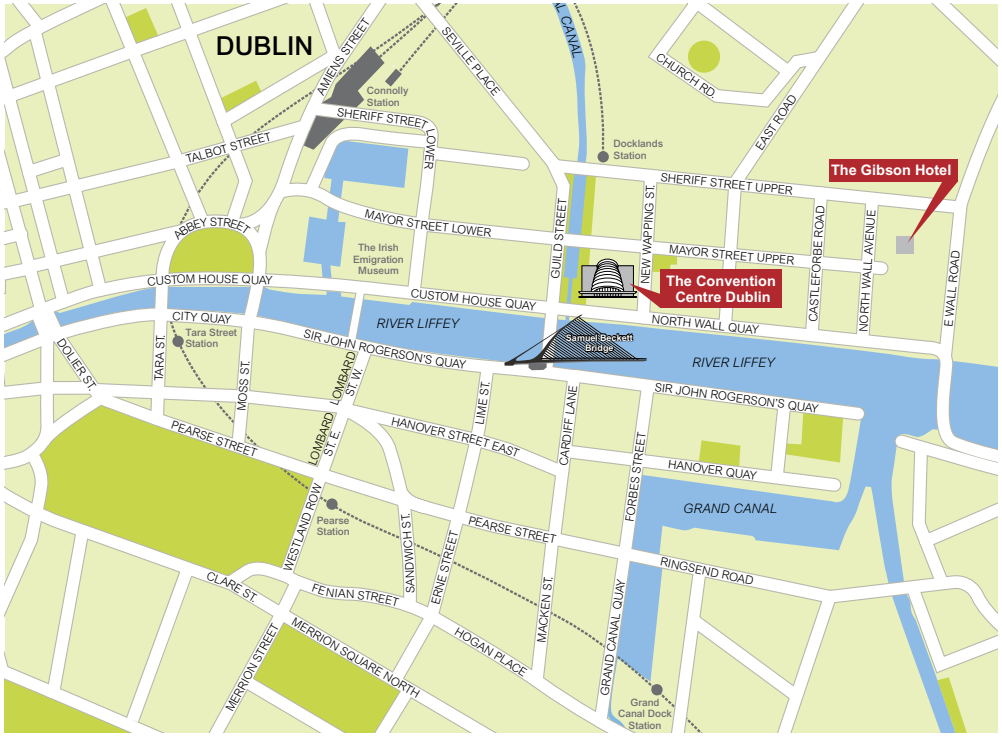
www.theccd.ie



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