2nd European QA Conference

27–29 April 2016

European harmonised quality, wouldn't it be NICE

Delegate brochure

Conference Sponsor

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European harmonised quality,

The European QA Conference Programme Committee invites you to the second European QA Conference, to be held in **Nice, France during the 27-29 April 2016.**

The conference

The aim is to have a full European QA Conference involving European regulatory authorities and European QA Societies. The conference will consist of plenary, parallel and workshop/ interactive sessions together with a large exhibition and poster area.

This is Europe's largest QA Conference, so this is an excellent opportunity for all European QA Societies to promote and share experiences, consider regulatory and guidance updates, to exchange information and hear from European regulators.

The Conference Programme will cover the following GxP areas both in general presentations and for some areas, their own individual streams:

- **Good Clinical Practice**
- **Good Laboratory Practice**
- **Good Manufacturing Practice**
- **Good Pharmacovigilance Practice**
- **Information Technology**
- **Medical Devices**
- **Non Regulated Scientific Research**
- **Animal Health**

All presentations will be made in English.

For additional information and registration forms visit the European QA Conference website at

www.european-qa-conference.com

There are also a number of advertising and sponsorship opportunities available together with full exhibitor packages.

Pre-conference training

We will also run some pre-conference training on Monday 25 April and Tuesday 26 April 2016. Details of this training can be found on the website at:

www.european-qa-conference.com

The European QA Conference will be held every three years, with the next one being held in the spring of 2019.

wouldn't it be NICE

The venue

The venue for the 2nd European QA Conference is the world renowned Nice Acropolis in Nice, France.

The Nice Acropolis is a multi-purpose venue capable of hosting conferences, annual general meetings, symposiums, conventions, exhibitions, trade shows, seminars, receptions, galas, performing arts and sporting events and more.

Its size, state-of-the-art equipment and modular spaces make it one of the most versatile convention and exhibition sites in Europe.

Nestled in the heart of downtown Nice, just 15 minutes from the airport, the Nice Acropolis Convention and Exhibition complex offers you: five auditoriums with 250 to 2,500 seats, 50 meeting rooms with 20 to 800 seats and a 26,000 sqm exhibition hall. The facilities boast modular configurations that can be easily rearranged to suit the most demanding needs.

Nice is second only to Paris as a destination for international business travellers in France. The city is popular for its ease of access: its airport, the second largest in France, offers direct service to 90 destinations in more than 40 countries. Nice also has the largest offering of hotels in France, after Paris, and most are located in the city centre.

With more than 900 hotel rooms in the immediate vicinity of the Nice Acropolis, it can host the biggest events in the industry.

The city's seaside location and exceptional sunshine (yearly average: 300 days) make Nice a destination of choice for your next event. As soon as you arrive, you'll enjoy the exotic charm of the celebrated, palm tree-lined 'Promenade des Anglais'. During your free time, you can sample local specialities (pissaladière, socca, farcis niçois...) and admire the warm, ochre façades of the Vieux Nice (the old town).

The Novotel Nice Centre is the main conference hotel which is situated just across the road from the Nice Acropolis. The airport at Nice Côte d'Azur is a mere 15 minutes away, and it is a short walk to the historic centre of Vieux-Nice, with its charming alleys and traditional backstreets. The Nice tramway runs just outside the hotel, to take you in comfort to the Place Masséna, the city's beautiful central square, to the shops on Avenue Jean Médecin in ten minutes, or to the famous Promenade des Anglais.

The hotel has complimentary wifi in all its 180 rooms, its roof-top panoramic pool is the perfect base, whether you are travelling on business or on holiday with your family.

www.novotelnice.com/home/novotelnicehotels.shtm

Wednesday
27 April 2016

Morning

Plenary Sessions

8.00 **Conference registration**

9.15 **Opening address**

Laurent Bouillot, SOFAQ

Session 1
Smart Quality

Chair: Laurent Bouillot, SOFAQ

Keynote speaker

9.30 **Global pharmaceutical regulation: Plea for further harmonisation**

Thierry Bourquin, Sanofi

- Key actors of the pharmaceutical regulations (international and local regulators)
- The role of pharmaceutical industry and technical associations
- Some success stories…
- …but harmonisation is far from being achieved
- Hints for the future

10.30 **Refreshment break**

Session 2
Smart Quality

Chair: Kerstin Koenig, Merck

11.00 **Considerations for the use of Electronic Media and IT Tools in Clinical Trials**

Gabriele Schwarz
Federal Institute for Drugs and Medical Devices

- General considerations
- Electronic Trial Master Files (TMF) & electronic Investigator Site Files (ISF) with focus on the generation of electronic certified copies
- Use of electronic media for the Informed Consent Process

11.45 **A TransCelerate QMS – Issue Management Conceptual Framework – From Challenges to Opportunities**

Susan Callery-D'Amico
AbbVie

- Summarise the challenges of Issue Management within our industry due to complexities in development
- Explanation of how a type of triage mechanism can tame and sort the plethora of issues in order to focus on issues that matter and impact the clinical development efforts
- Use of methodologies that should bring about a decrease in issues of impact and considerations that effective management of issues can be the key driver for ensuring a state of control, continuous improvement and confidence in data

12.30 **Lunch**

Stream 1

Afternoon

Session 3
Data integrity – are we still in control?

Chair: Sarah Pickersgill, Celerion

14.00 **Ensuring data integrity – mitigation of risks**

Wolfgang Schumacher
F. Hoffmann – La Roche Ltd

- Regulations, warning letters and inspection observations
- How to ensure data integrity during GxP system development lifecycle
- Validation Paradigm shift
- Data integrity review process with examples
- Data integrity audit

14.45 **Data integrity QA how monitoring discovery activities can inform GxP oversight**

Jon Bartlett
GlaxoSmithKline

The drivers, aims and scope of GSK's data integrity oversight for discovery/non-GLP work

- Lessons learned from the programme
- Why data integrity is not just about computer systems
- How considering an end-to-end data lifecycle can inform oversight in the mature GxP space

15.30 **Refreshment break**

Session 4
Data integrity – are we still in control?

Chair: Helmuth Morgenthaler, DGGF

16.00 **OECD advisory document 'The application of GLP Principles to Computerised Systems'**

Ronald Bauer
Austrian Agency for Health and Food Safety

- What is new in the new OECD IT Document in comparison to Consensus Doc No.10?
- Key elements of computerised system validation are similar in all GxPs, therefore the content of the new document is based upon the systematics of the EU GMP Guideline Annex 11 in consideration of the PIC/S Good Practices for Computerised Systems
- A new global public hearing process to consider stake holder options of the member countries has been conducted

Wednesday
27 April 2016

16.45 Current practices of electronic archiving in the GLP environment – field reports from Sanofi-Aventis and Boehringer Ingelheim

Andreas Kirchhoff
Boehringer Ingelheim &

Joerg Roesser
Sanofi-Aventis Deutschland GmbH

- How to define: Raw data and electronic archiving
- The regulatory benchmark: OECD Advisory Document No.15
- Current implementation of electronic archiving systems and processes (at Sanofi-Aventis & Boehringer Ingelheim)
- Ongoing activities with regard to long-term stable data formats – workarounds and future perspectives

17.45 – 18.45 'Meet the Delegates' drinks reception

Rue Pairoliere, a quaint shopping street in Old Town Nice.

Stream 2

Afternoon

Session 3
CAPA

Chair: Angelika Tillmann, Chiltern

14.00 Root Cause Analysis and CAPA management

Eileen Lumsden
GlaxoSmithKline

People and technical skills required to:

- Determine a Root Cause
- Develop appropriate CAPAs
- Manage CAPAs

14.45 CAPA Effectiveness

Friederike Spengler
Chiltern

- CAPA Procedures
- Defining CAPA Effectiveness
- Measuring CAPA Effectiveness
- Timing of CAPA Effectiveness
- Improving CAPA Procedures and Effectiveness

15.30 Refreshment break

Session 4
QMS

Chair: Allison Jack, GlaxoSmithKline

16.00 Lean Quality Management Systems

Lena Vågberg
AstraZeneca

- The requirements of a QMS – we all know them!
- What can Lean mean in QMS?
- What does good look like? Let's review if there are best practices and what they look like. Do we really need all the SOPs and documents we have? Can we make it simpler
- A Lean QMS – how can we make it happen? Discussing the steps we need to take to influence

16.45 QM Systems, blended or singles?

Alain Piton
ALP Quality Systems

- Integrated (GxP) versus separated (GLP, GMP, GCP, GDP, GVP…) QMS
- Multi-disciplinary approach of internal and external audits, pros and cons
- How to defend an integrated approach during regulatory inspections when inspectors prefer separated systems

17.45 – 18.45 'Meet the Delegates' drinks reception

Thursday
28 April 2016

Stream A

Morning

Session 1
Risk Management

Chair: Kerstin Koenig, Merck

9.00 Challenges for implementing an efficient risk management system example of ICH Q9

Olga Croso Bonnier
Sanofi Pasteur

- Principles and tools
- Challenges and success factors

9.45 Risk management versus quality management

Kevin Perkins
GlaxoSmithKline

- Concepts and key components of risk management and quality management
- Risk management and quality management tools
- Overlaps and linkages
- Complementary or not?

10.30 Refreshment break

Session 2
Risk Management

Chair: Lars-Eric Ellow, Key2Compliance AB

11.00 How ISO standards have influenced Quality Risk Management

James Vesper
LearningPlus, Inc.

In this presentation, several ISO standards that emphasise risk management will be discussed along with how industry's use of QRM and national authorities' expectations are changing

11.45 ISO 14971 – Risk management for medical devices

Anette Sjögren
PREVENTIA AB

- Today's background and status of ISO 14971
- Risk analysis according to ISO 14971
- ISO 14971 – how to apply and what are the interfaces
- Risk management and process interfaces

12.30 Lunch

Stream A

Afternoon

Session 3
Good Clinical Practice

Chair: Brigitte Damour, ICON

13.45 FDA Inspections at sponsors from 2011-2015

Rita Hattemer-Apostel
Verdandi AG

- The results of analysis of FDA Warning Letters issued to sponsors between 2011 and 2015 will be presented and discussed
- What do the Warning Letters reveal? Any trends? Any surprises?
- How do they compare to EMA inspection results? Any/which differences? Any surprises?
- How do the results compare with our own audit experiences?
- Conclusions and outlook

14.30 Risk-based monitoring – Are we losing the plot?

Paul Strickland
Strickland Quality Assurance Ltd

- Why the regulator wanted us to make the change
- Who's responsible for site quality?
- What's happened when RBM have been inspected?
- Has it made the world a better, simpler place?

15.15 Refreshment break

Session 4
Good Clinical Practice

Chair: Chris Shepherd, GlaxoSmithKline

15.45 Good Clinical Practice QA Clinic

Discussion on current GCP topics and challenges within industry

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Thursday
28 April 2016

Stream B

Morning

Session 1
Inspection Strategies Management

Chair: Catherine Liang, WIL Research

9.00 Practical look at inspection behaviour

Alun Maxwell
Bringing Your Training To Life

An interactive session to look at inspection behaviour on how to interact with inspectors

9.45 Good Pharmacovigilance Practices (GvPs) – the relevance for GCP/GMP

Shelley Gandhi
NDA Regulatory Science Ltd

- Classification and example findings
- Inspection preparation and follow-up
- Interaction between sponsor and authority

10.30 Refreshment break

Session 2
Inspection Strategies Management

Chair: Christiane Hartlieb-Walthor-Sano, Pro-TS Professional Trial Services

11.00 Inspections of bioequivalence trials: examples of findings and perspectives

Olivier Le Blaye
ANSM

- Major and critical observations are very often made during inspections of bioequivalence trials
- As seen recently, the consequences of these findings can be significant
- Corrective and preventive actions are currently discussed with sponsors and applicants

11.45 GCP Inspections – Lessons Learned?

Eva-Maria Jahn
Paul-Ehrlich-Institut

- Classification and examples of findings
- Inspection preparation and follow-up
- Interaction between sponsor and regulator

12.30 Lunch

Stream B

Afternoon

Session 3
Good Laboratory Practice

Chair: Paul Davidson, Headway Quality Evolution

13.45 Risk-based QA in a GLP environment – is it possible?

Vanessa Grant
Envigo

- UK MHRA position paper on implementation and maintenance of a GLP QA monitoring programme
- Moving this forward within Europe
- Practical tips for implementation

14.30 A glimpse to the global CRO market

Herman Lehn
Lehn Consulting

- Oversight on the global CRO market
- Identification of the 'right' CRO
- Benefits, risks and pitfalls when working with CROs

15.15 Refreshment break

Session 4
Good Laboratory Practice

Chair: Ulrich Schepers, BASF

15.45 Good Laboratory Practice Round table

Confirmed participants to date:

Andrew Gray
UK

Ronald Bauer
Austria

Wolf Bulling
Germany

Francisca Liem
USA

Round table discussion with members of the GLP Monitoring Authorities on current GLP issues/topics/challenges within industry

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Thursday
28 April 2016

Stream C

Morning

Session 1
Standards to Support Life Sciences

Chair: Lars-Eric Ellow, Key2Compliance AB

9.00 ISO 13485 – Quality management for medical devices; relationship to other quality management systems and its future

Anette Sjögren
PREVENTIA AB

- Background to ISO 13485
- Future of ISO 13485
- ISO 13485 – its relation to the EU GMP, US 21 CFR 820 and other regulatory quality management systems for medical devices
- ISO 13485 interfaces with other ISO standards

9.45 ISO 10993 Standard for Biocompatibility

Monica Grekula
Symbioteq AB

- What is Biocompatibility?
- Is medical device toxicity different from pharma
- Medical devices and standards: ISO 10993/ISO 14971/ISO 13485/ISO 14155
- Biological evaluation medical devices – the ISO 10993 standard series

10.30 Refreshment break

Session 2
Standards to Support Life Sciences

Chair: Paul Davidson, Headway Quality Evolution

11.00 Regulatory expectations for human tissue research

Anthony Chadwick
Covance

Human tissue research, a changing target throughout the sample lifecycle from source to disposal

11.45 Practical use of the Revised Cleanroom Standards ISO 14644 Part 1 and Part 2

Matts Ramstorp
BioTekPro AB

- The major changes in ISO 14644 Part 1
- The major changes in ISO 14644 Part 2
- The practical impact of these changes
- The 5 µm 'challenge' in Annex 1

12.30 Lunch

Stream C

Afternoon

Session 3
Good Pharmacovigilance Practice

Chair: Sanjay Motivaras, Audit PV Ltd

13.45 Four years later: Have the GVP modules really increased patients safety?

Susanne Kienzle-Horn
SCRATCH PV GmbH

- What was the plan?
- Signal detection: the needle in the haystack
- Compliance: important to monitor- or important because monitored
- Goals achieved?

14.30 Benchmarking Survey on the PV System Master File

Calvin Johnson
AbbVie

An overview of the RQA industry benchmarking survey on the PV System Master File

- Practical aspects regarding the implementation
- Challenges and best practice regarding maintenance
- How the PSMF is used internally and externally
- Regulatory authority feedback

15.15 Refreshment break

Session 4
Good Pharmacovigilance Practice

Chair: Bianca Scholz

15.45 PV QA round table with regulators

Jo Harper
MHRA

Diane Halle
ANSM

Nele Matthijs
FAMHP

And an EMA representative

Discussion on 'grey areas' in the GVPs:

- Module I Quality Management System
- Module II Pharmacovigilance System Master File
- Module IV Pharmacovigilance Audits

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Thursday
28 April 2016

Stream D

Afternoon

Session 3
Good Manufacturing Practice

Chair: Nadine Frankenberg, Synlab Pharma Institute AG

13.45 Simplification of Quality Management Systems (QMS)

Verena Wieser
Baxalta Innovations GmbH

A new QMS will enable you to:

- Improve compliance
- Simplify work processes
- Remove distractions and other non-value added work that gets in the way of our day to day operations
- These efforts to simplify and harmonise a QMS will be an important enabler of success as a company

14.30 Management review and quality metrics

Christian Gausepohl
Rottendorf Pharma GmbH

The management review process

- Additional workload or opportunities for the QP?
- Making the best of it without entangling ourselves
- Significance for continuous improvement

Quality metrics

- New requirements
- GMD (give more data)
- Quality performance

15.15 Refreshment break

Session 4
Good Manufacturing Practice

Chair: Nadine Frankenberg, Synlab Pharma Institute AG

15.45 Good Manufacturing Practice QA Clinic

Discussion on current GMP topics and challenges within industry

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Stream E

Afternoon

Session 3 Commercial/Academia

Chair: Tim Stiles, Qualogy

13.45 Scientific integrity within the university setting

Patricia Henley
London School of Hygiene and Tropical Medicine

Regulatory compliance and quality systems are not terms that are immediately embraced within an academic environment

So how should we approach the challenge of implementing processes that not only assist with scientific integrity of the work performed but are also seen as beneficial within the academic research community

14.30 RQA and Global Engagement

Tim Stiles
Qualogy

A presentation on the plans and actions of RQAs Global Engagement Team to engage with the wider research community

15.15 Refreshment break

Session 4 Medical Devices

Chair: Colette McIntyre, HeartSign Technologies Ltd

15.45 Medical Devices QA Clinic

Discussion on the current Medical Devices topics and challenges facing industry

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Stream F

Afternoon

Session 4 IS/IT

Chair: Helmuth Morgenthaler, DGGF and Sarah Pickersgill, Celerion

15.45 Computer system validation

16.30 Cloud computing

A mix of short presentations and discussions regarding key Computing System Validation principles and challenges in a GxP environment

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Stream G

Afternoon

Session 4 Animal Health

Chair: Catherine Liang, WIL Research

15.45 Animal Health QA Clinic

Discussion on current Animal Health topics and challenges within industry

19.00 Pre-dinner drinks reception

19.30 Dinner dance

Friday
29 April 2016

Morning

Session 1
European Harmonised Quality

Chair: Steffen Koenig, DGGF

09.00 Social listening for Post-Marketing Safety Surveillance

Cath Harvey
GlaxoSmithKline

- What promise does social listening offer pharmacovigilance?
- How can social listening augment current pharmacovigilance strategy?
- What risks are associated with this capability and how can these be mitigated?
- Development of an overall governance framework
- Security of cloud based systems

09.45 EMA Update

Anabela Marcal
EMA

The presentation will cover updates from the European Medicines Agency on current topics.

Detailed information will follow in due course.

10.30 Refreshment break

Session 2
European Harmonised Quality

Chair: David Butler, RQA

11.00 GLP global overview – OECD Working Group and EPA compliance monitoring updates

Francisca Liem
EPA

- Recent updates of OECD GLP Working Group activities
- US EPA GLP regulatory and enforcement actions

11.45 Closing address

David Butler, RQA

12.15 Close of conference

Boats in the port of Nice.

Dinner Dance
Thursday 28 April 2016

Conference Dinner Dance Nice Acropolis

Join your fellow delegates for a special evening at the Nice Acropolis on the 28 April 2016.

Pre-dinner drinks at **19.00**
followed by dinner (including wine) at **19.30**

After dinner, dance the night away until midnight.

Dress code: **black tie/suit and ballgowns**

The cost of the dinner dance is included in the full delegate registration fee. Two day delegates can also purchase a ticket when registering for the conference.

Information

Meeting Organiser

Research Quality Association
3 Wherry Lane, Ipswich
Suffolk, IP4 1LG
United Kingdom

Tel: +44 (0)1473221411
Email: conferences@therqa.com
Website: www.european-qa-conference.com

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Conference registration fees

Full Delegate Package includes:

- Registration to the full conference
- Refreshments on Wednesday, Thursday and Friday
- Drinks reception on Wednesday evening
- Lunch on Wednesday and Thursday
- Pre-Dinner Drinks Reception and Dinner Dance on Thursday
- Conference material.

Full Delegates Registration Fees

Members
€600 plus tax – until 28 February 2016
€659 plus tax – from 29 February 2016
These member rates apply to members of RQA, DGGF, SOFAQ and any other European QA Societies.

Non-Members
€659 plus tax – until 28 February 2016
€709 plus tax – from 29 February 2016

Two Day Delegate Package includes:

- Registration to two days at the conference
- Refreshments on the two days
- Lunches on the two days (please note there is no lunch on Friday)
- Drinks reception on Wednesday evening if this is one of your days chosen.

(Please note this package does not include the Pre-Dinner Drinks Reception and the Dinner Dance on Thursday. Separate Dinner Dance tickets need to be purchased for this – see below).

Members
€484 plus tax.
These member rates apply to members of RQA, DGGF, SOFAQ and any other European QA Societies.

Non-members
€533 plus tax.

Dinner Dance tickets
Dinner Dance tickets (for two day delegates or additional Dinner Dance guests).
Members and Non-Members €65 plus tax.

Tax
Tax (where applicable) is currently 20% in France.

Delegate registration

To register for the conference please use the following link:
https://therqa.typeform.com/to/bdd9kA

Terms and conditions

Delegate Cancellation

All conference cancellations must be received in writing. For all cancellations an administrative fee of €100 plus VAT will be charged. No refunds can be made for cancellations received after 28 February 2016. Registrations may be transferred to another person at any time and incur a €40 amendment fee.

Please note that the organisers cannot be held responsible for any liabilities caused by the potential cancellation of the conference due to unforeseen circumstances. The organiser cannot accept liability for accidents, injuries and losses that might occur.

The conference programme is subject to modifications.

By booking online you are agreeing to these terms and conditions.

Hotel accommodation

The conference hotel is the Novotel Nice Centre and special rates have been agreed with the hotel. All accommodation is booked direct with the Novotel Nice Centre. A small allocation of rooms is held at the hotel for the conference along with special conference rates. To book your accommodation please use the booking form which can be found on the Novotel Nice section of the website.

There are numerous other hotels close by to the Nice Acropolis.

Hotel rates
Single occupancy bed and buffet breakfast €171.25 per room per night including city tax.
Double occupancy bed and buffet breakfast €189.50 per room per night including city tax.

Transportation in Nice

Tourist Office Nice
http://en.nicetourisme.com/

Nice Airport
http://en.nice.aeroport.fr/

Transport by bus from the airport to city centre
http://www.bestofniceblog.com/transport-in-nice/getting-to-and-from-nice-airport/

Nice Railway Station
http://www.gares-sncf.com/fr/gare/frnic/nice

The railway station is only a five minute taxi ride to the Nice Acropolis.

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DGGF GERMAN SOCIETY FOR GOOD RESEARCH PRACTICE

SOFAQ FRENCH QUALITY ASSURANCE SOCIETY

RQA Research Quality Association