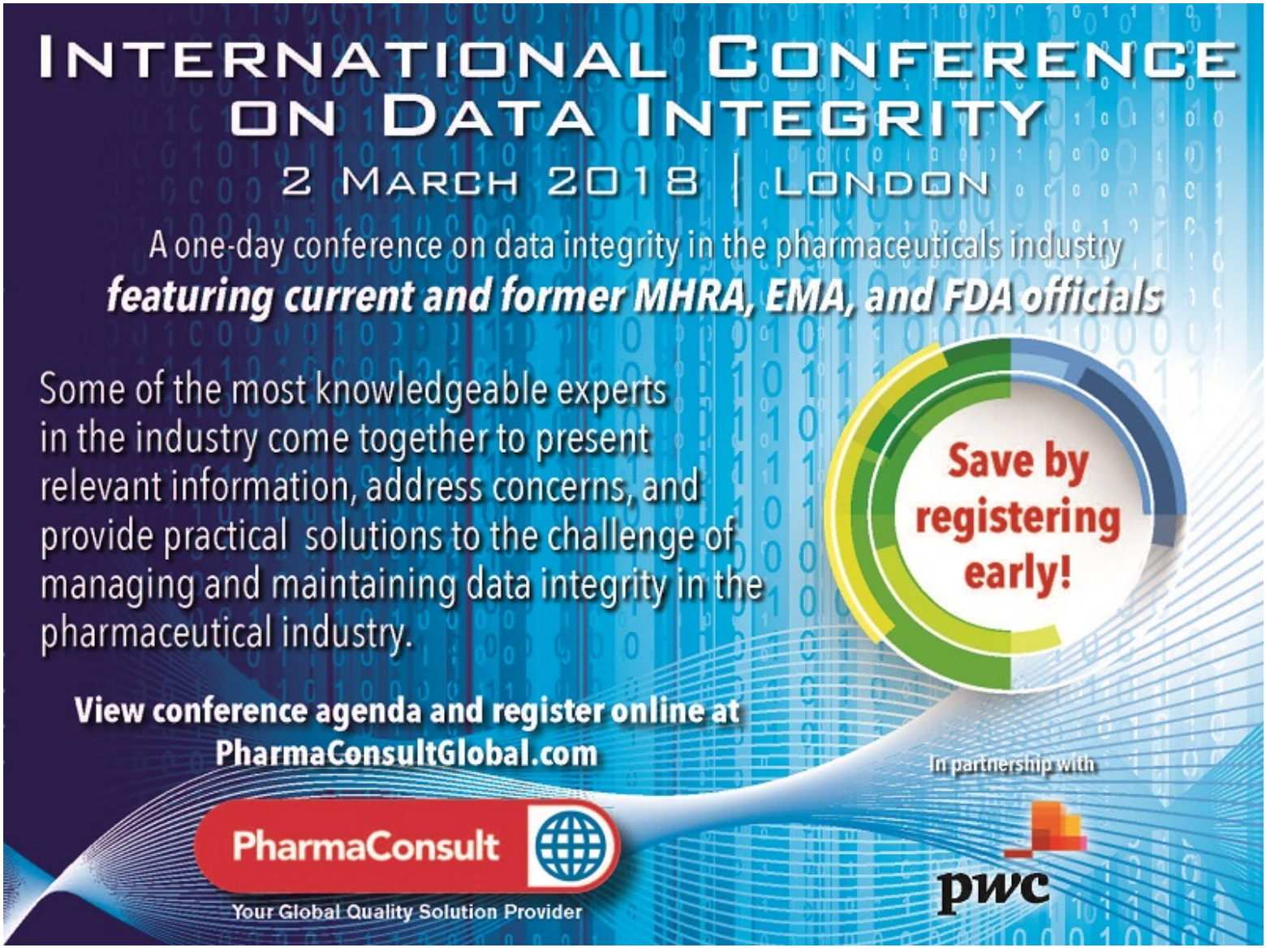
First International Conference on Data Integrity in Pharmaceuticals

Conference Location: PriceWaterhouseCoopers, 1 Embankment Place
London WC2N 6RH
Conference Chairmen: Professor Gino Martini
A One-Day Conference
2 March 2018

Early Bird Registration £700 before 1st February



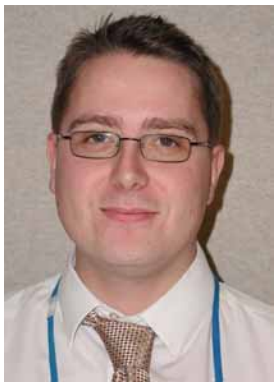
Register Online at www.PharmaConsultGlobal.com

The Program

Time	Topic	Speaker
Morning Session: The Regulatory Environment		
7:30 – 8:30	Registration and continental breakfast	
8:30 - 8:40	Welcome	
8:40 – 9:10	The EMA/FDA Mutual Recognition Agreement and Data Integrity	David Cockburn, ex-EMA
9:10 – 9:50	Behavioral Elements of Personnel That Can Lead to Data Integrity Issues with a summary of data integrity observations in inspections	Stephen Grayson, Expert Inspector in MHRA's GMDP
9:50 -10:10	Q&A Session	
10:10 - 10:30	Break	
10:30 - 11:00	Ensuring Data Integrity: The MSD Approach	Geoffrey Williams,MSD
11:00 – 11:30	Annex 16: The critical role of the QP in preventing and resolving data integrity issues of: • GMP compliance of API and Excipients. • Qualification of materials in *Supply chain*	John D. R. Jolley, ex Boehringer Ingelheim
11:30 - 12:00	The Impact of GAMP V on Data Integrity Discussions	Guy Wingate, GlaxoSmithKline
12:00 – 12:30	Q&A plus open discussion with morning speakers	
12:30 – 14:00	Lunch	
Afternoon Session: Company Efforts and Responsibilities to Mitigate Data Integrity Concerns		
14:00 – 14:30	Cyber Security/Data Privacy: Critical Concerns for Pharmaceutical Data	Jo Pisani, PWC
14:30 – 15:00	Practical Challenges to Data Integrity from Routine Business Practices	Steven Brown. Novartis
15:00 – 15:30	Data integrity in supply chains and traceability systems: implications of the FMD	Mark Davison, BlueSphere Health
15:30 - 15:50	Break	
15:50 – 16:20	Customizing an audit program to evaluate data integrity concerns and to identify root causes for data integrity	David Thompson, Clarity Compliance
16:20 – 16.50	Reporting self-identified data integrity issues to Regulatory Authorities and Responding to data integrity inspectional observations	Gary Bird, Ph.D., RPS; ex-FDA
16.50-17-15	Q&A plus open discussion	

The Speakers

Gary Bird, Ph.D. is currently President, PharmaConsult-US, LLC, and Director, PharmaConsult Global, Ltd., an international cooperative supplying GXP quality consulting services. He has served as Vice President, Regulatory Affairs and Quality at Geno, LLC and Director of Corporate Quality for GTx, Inc. (Memphis, TN, USA and was responsible for confirming all non-clinical (GLP), manufacturing (GMP), and clinical trial (GCP) related activities were conducted in compliance with appropriate laws and regulations. Prior to joining GTx, he was with Eli Lilly and Company from 1995 to 2003, serving as Senior Quality Advisor for Biotechnology in Corporate Quality Assurance and Senior Regulatory Consultant, CMC Regulator Affairs. He was with the FDA from 1990 to 1995 in both CDER and CBER where he was Assistant to the Deputy Director. During his time with Lilly and FDA he represented both PhRMA and the FDA in the International Conference on Harmonization negotiations on four (4) different agreed guidances. He approved and signed documents on behalf of both organizations. He was secretary for all ICH Working Committees for documents on which he worked including Biotech Stability (Q5C), Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process (Q5E); Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (Q6B) and The Common Technical Document for CMC Submissions (M4).



Steven Brown is a member of the Novartis Technical Operations Regional DI Team, with oversight of data integrity activities within Novartis' European manufacturing facilities. Steven has worked within data integrity for over 2 years, prior to this Steven has extensive experience within the API manufacturing environment. Steven has also presented at PDA and JPAG data integrity symposiums.

David Cockburn BSc (Hons) is a former member of MHRA and EMA. Head of the Manufacturing and Quality Compliance Service with, among other things, responsibility for GMP inspection coordination, managing of quality defects with centralised products and working with EDQM on the sampling and testing of centralised products. He also held the chair of the GMP/GDP Inspectors Working Group which provides expert input on the development of EU GMP for the European Commission and develops harmonised inspection standards and procedures for GMP inspectorates of the EU National Competent Authorities.

After 5 years in the pharmaceutical industry, which included 4 years as a section head managing the production of a variety of different sterile and non-sterile dose forms at Glaxo Operations in the UK, David became a GMP inspector for the UK authority now known as MHRA. Over a period of 14 years David conducted many GMP inspections in the UK and overseas as well as GDP inspections within the UK. Prior to leaving EMA David was the David worked for the European Medicines Agency (EMA) for 15 years and was EU technical lead working with US-FDA on mutual reliance in GMP inspections culminating in the signing of the EU-USA Mutual Recognition Agreement in 2017.

Mark Davison heads the European operations of rfxcel, a leading serialisation solution provider. He is also a well-known expert and author in the field of drug traceability, anti-counterfeiting and other issues pertinent to the Falsified Medicines Directive and its equivalents worldwide. He worked in anti-infectives R&D at GlaxoSmithKline before a commercial career spanning biotech, CROs, consulting and software. He is the author of "Pharmaceutical Anti-Counterfeiting" (Wiley).

Stephen Grayson joined the MHRA in January 2007 as an Inspector following 24 years' experience of biopharmaceutical manufacturing. He was later was promoted to Senior Inspector and is the MHRA inspectorate lead on computerised systems and a member of the MHRA data integrity reference team, who were responsible for, amongst other things, the drafting of the MHRA data integrity guidance. He has been involved in many inspections with a data integrity focus, including international multi-agency inspections.

John Jolley qualified as a Pharmacist and has over 30 years' experience working in the pharmaceutical Industry and Primary Health Care Companies. He founded Pharma Consult in 2006 and cofounded Pharma Consult Global in 2013, which is registered as an SME with the EMA that provides Regulatory and HealthCare Technology consultancy and training in Europe as well as; USA and Canada, Latin America, Far East, Middle East, Russia and India.

John has a degree in Pharmacy and is registered as a Practising Pharmacist as well as a Qualified Person (QP). He has held positions in Clinical Research, Product Registration, Manufacturing, Quality Assurance, Medicines Management and General Management.

He has been awarded fellowships by the Royal Pharmaceutical Society (RPS) and the Chartered Quality Institute (CQI) and is registered as a Senior Consultant qualified to conduct GMP/GDP compliance audits. Before coming to work in Technical Consultancy John was Technical Director of Boehringer Ingelheim UK for 15 years and before that CEO of a Beecham Products subsidiary in Ireland, he now works in a leading Phase 1 Clinical research organisation, and, Richmond Pharmacology in London as well as being Managing Director of Pharma Consult.

Professor Gino Martini, Ph.D., is a registered practicing Industrial Pharmacist and a Fellow of the Royal Pharmaceutical Society. Professor Martini divides his time between the Pharmaceutical Industry and King's College London as a Visiting Professor in Pharmaceutical Innovation, after having held the Chair in Pharmaceutical Innovation at King's for 5 years. Prior to that Professor Martini spent over 17 years working at GlaxoSmithKline Pharmaceuticals, Roche Product Ltds and Shire Pharmaceuticals working in a variety of Commercial, Innovative Technology based and Medical Affairs roles, directing groups in the US, Europe and Emerging Markets.

Professor Martini is Chief Scientist Designate for the Royal Pharmaceutical Society. Professor Martini has a MBA specializing in SME success and business failure awarded with Distinction from the University of Liverpool. Professor Martini is Chair of the Industrial Pharmacists Group of the Royal Pharmaceutical Society and also a member of the ABPI Academic Network. In 2016, Professor Martini was appointed a Fellow of the European Industrial Pharmacists Group.

Jo Pisani, PriceWaterhouseCoopers is currently UK Pharma and Lifesciences Consulting Leader, PwC Strategy&. She has over 20 years' experience in the sector in Consulting and in industry roles with GSK. She assists clients with strategic issues. Her focus areas are developing new business models for innovation and commercial, technology enabled strategies and market entry strategies. She is an advisory board member for MedCity. She is a regulatory commentator on key industry topics such as AMR, Brexit and industrial strategy.

David Thompson is a Computer Systems Validation and Compliance expert. He has worked in the IT/Computer Systems arena for almost 30 years, the last 18 years he has provided Consultancy, Auditing and Training to the pharmaceutical/biotech and healthcare industry across the UK, Europe, Far East, Asia and the U.S.A.

Working across a wide variety and scale of organisations (Top 5, mid-sized, generics, medical devices, CMO;s, CRO's), he has an established pedigree of bringing his experience in technical, procedural methodologies and project implementations to site, country and global projects/programs for the benefit of his clients.

Recent activities include Global Head of Quality for GxP SaaS global program and also delivering Data Integrity Auditing, Consulting, Training and Program Implementations weaving Data Integrity into the organisational fabric of clients in the UK, Italy and the USA.

He is a Chartered Engineer with both the MIET and the MInstMC and a member of the GAMP MES SIG and GAMP DI SIG.

Photograph Pending

Geoffrey Williams, Ph.D.

Guy Wingate. Ph.D. is Vice President and Compliance Officer for Global Manufacturing & Supply (GMS) at GSK is responsible to assuring robust internal control frameworks and effective risk management is in place across the integrated manufacturing and supply chain managed by GMS. Duties include overseeing investigations into potential breaches of corporate policy and company values, Third-Party Oversight risk management for the whole of GSK, and provides compliance support to the GSK Global Procurement organisation. He is a member of the GMS Executive Leadership Team and previously acted as Global Risk Officer supporting the GSK Corporate Executive Team Risk Oversight & Compliance Committee between 2013 and 2015.

He chaired the International Society of Pharmaceutical Engineers (ISPE) GAMP group for ten years up to 2010 and was the task team leader for the acclaimed GAMP5 computer compliance industry guide. He is also part of the team who produced the popular ISPE/GAMP Guide on Records & Data Integrity.

Dr. Wingate is a Chartered Engineer and Fellow of the Institute of Engineering and Technology. He holds a B.Sc., M.Sc., and PhD. from University of Durham in Computing, Advanced Electronics and Engineering Science respectively. He is widely published in journals and books, and has regularly chaired and spoken at validation conferences in the UK and Europe. Dr. Wingate was Visiting Lecturer for the University of Manchester's M.Sc. course on Pharmaceutical Engineering Advanced Technology (PEAT) and Institute of Dublin's M.Sc. course on Validation Sciences between 1996 and 2008. He was also a member of the ISPE International Board of Directors between 2008-2012.

Venue: PriceWaterhouseCoopers, 1 Embankment Place, London, WC2N 6RH
Telephone: 020 7583 5000
For directions to the venue **see** https://www.pwc.co.uk/assets/pdf/ep-location-map.pdf

Hotel: Delegates may book directly with the hotel by using the following information

AMBA Hotel, Charing Cross www.amba-hotel.com/
Group Reference: **PHAR010317**
1 March 2018 for one (1) night

Double: £**205.00** per room per night based on single occupancy including VAT & full English breakfast
Deluxe: £**215.00** per room per night based on double occupancy including VAT & full English breakfast