

## REGISTRATION FORM

### Perspectives on Analytical Data Integrity in a Pharmaceutical Quality System.

The meeting will take place in the Council Room of The Chemistry Centre, Burlington House, Piccadilly, London. Attendance is limited, so early registration is recommended.

To register for this meeting, please complete and return the form below to: **Brian Woodget, Honorary Secretary, East Anglia Region of the Analytical Division of the RSC at: [bwoodget1@sky.com], or e-mail with details as below**

Registration fees for attending are: **RSC/JPAG members £80, non-members £110, student/retired members and unwaged £40. Registration fee to include tea/coffee on arrival and lunch.**

Payment may be made by BACS or by cheque. We are unable to take credit card payments. Following registration you will be advised of payment details

Delegate name:.....

Affiliation:.....

Address for  
correspondence:.....

.....

.....

Tel:..... Mobile: .....

E-mail:.....

I do/do not have any special dietary requirements – please specify if necessary .....

Delegates are advised that there are no parking facilities at Burlington House



Analytical Division, East Anglia Region

one day meeting entitled:

### Perspectives on Analytical Data Integrity in a Pharmaceutical Quality System.

to be held on:

**Tuesday 17 November 2015**

at

**The Chemistry Centre,  
Burlington House, Piccadilly,  
London, W1J 0BA**

Registered Charity Number 207890

This seminar will focus on the challenges associated with the generation of data in the pharmaceutical/biopharmaceutical GMP regulated Quality Control laboratory environment and will examine the impact of the MHRA Guidance for Industry regarding the maintenance of GMP data integrity throughout its lifetime.

The views of Industry and vendors of major laboratory systems / software used in the generation, storage and retrieval of data throughout its lifetime will be explored to establish the challenges that need to be overcome to continue to maintain compliance with the regulations. The use of the latest data handling technology and, going forward - cloud storage will be reviewed.

The seminar will be of interest to laboratory managers and scientists as well as Quality Assurance, Information Technology and associated personnel working in these GMP regulated areas.

Note: alterations to this programme will appear on the East Anglia Region web site [[www.rsc.org/adearegion](http://www.rsc.org/adearegion)]

Travel directions for getting to The Chemistry Centre, can be found at [[www.rsc.org/locations - contacts/](http://www.rsc.org/locations-contacts/)]

## Programme:

10:00 – 10:30 Arrival / Welcome / Refreshments

10:30 – 10:40 Chairman's Introduction

10:40 – 11:25 Awaiting title for presentation (*Nichola Stevens, Director, Computer Systems Validation, ALERE Inc*)

11:25 – 12:10 'A Critical Review of the MHRA Data Integrity Guidance' *Dr R D McDowall, Director, R D McDowall, Ltd, Bromley, Kent.*

12:10 – 12:55 'Identifying Data Integrity Gaps in Analytical Systems: A Practical Approach.' *Dean Harris, Director of Computer Systems Compliance, Envigo*

12:55-13:55 Lunch / Networking

13:55 14:40 'Requirements for an Ideal Laboratory Informatics Solution - Illustrated by a Chromatography Data System (CDS)' *Dr R D McDowall, Director, R D McDowall, Ltd, Bromley, Kent*

14:40 -15:25 Data Integrity: An Instrument Supplier's Perspective *Paul Smith, Compliance Manager, Agilent Technologies UK Ltd.*

15:25-16:10 Cloud-Based Services in a GXP Environment *Keith Williams, Managing Director, Formpipe.GXP*

16:10-16:15 Final comments and close of meeting.