

# Current Method Development Strategies in Separation Science

## The Chromatographic Spring Symposium & Annual General Meeting

Paul Ferguson, Vice-President - The Chromatographic Society



## Agilent Technologies



The Chromatographic Society's Spring Symposium and Annual General Meeting will be held at the Merck Sharpe & Dohme (MSD) site in Hoddesdon (Hertfordshire) on Wednesday 19<sup>th</sup> and Thursday 20<sup>th</sup> May. The theme for the meeting is "Current Method Development Strategies in Separation Science". As is becoming the norm for this meeting, the Spring Symposium will be held over one-and-a-half days allowing for an extensive range of presentations from academics, industrial speakers and vendors, as well as significant exhibition and networking time.

The preliminary programme is shown below. The meeting will be preceded by a two-day method development training course (on the MSD site) provided by LC Resources's Dr John Dolan and will link seamlessly with the Symposium agenda. The course will be staged by HiChrom and further details can be found on the HiChrom website ([www.Hichrom.com](http://www.Hichrom.com)). Members of the Chromatographic Society attending this training course are entitled to a 10% discount on the registration fee.

Merck Sharpe and Dohme in Hoddesdon is the main UK research site for the pharmaceutical giant Merck. As the focus of the meeting will be on small-molecule method development (principally pharmaceutical), this is a very apt setting for this symposium. Once again Agilent Technologies have kindly agreed to be principal sponsor for the meeting, and the Chromatographic Society thank them for their continued support. The first plenary lecture will be presented by Dr Chris Welch of Merck (USA) who will discuss "Chromatographic Method Development in Support of Pharmaceutical Process Research". Dr Welch is one of the leading luminaries on separation science within the Merck organisation (particularly in the area of chiral analysis<sup>[1,2]</sup>) and will deliver an in-depth perspective to the challenges facing chromatographers in pharmaceutical research. The second plenary lecture will be provided by the world-renowned Dr John Dolan (LC Resources, USA) who will give a presentation on "Identifying Equivalent and Orthogonal Columns for HPLC Method Development". Dr Dolan is well

known for his method development courses and also his LC Troubleshooting column in LC/GC Europe and North America<sup>[3]</sup> as evidenced by hundreds of practical troubleshooting and research publications on the subject<sup>[4,5]</sup>.

Also that afternoon, there will be a session on the analysis of genotoxic impurities. Presentations in the session will be provided by Dr Remco Stol and Dr Tom van Wijk (Schering-Plough and Solvay Pharmaceuticals respectively, both from The Netherlands). This area of analysis is coming under greater scrutiny as medicinal regulatory authorities expand the list of compounds falling into this category and push down the required limits of detection and quantification. These well-known speakers in the field will provide their companies practical perspectives on how they are addressing these issues.

The second day will be opened with a session on 'Industrial Perspectives'. In this application based session the winner of the 2010 Chromatographic Society Jubilee medal Dr Roman Szucs (Pfizer Global Research &

Development, UK) will provide an insight into method development processes in a full-development pharmaceutical environment<sup>[6-8]</sup>. The presentation will focus on computational directed method development and is titled "Is in-silico chromatographic method development - a myth or a real possibility?". The second presentation in this session will be provided by Dr Rudy Sneyers (Johnson & Johnson, Belgium)<sup>[9-10]</sup> who will discuss "COSMOS... A Science-based Strategy in Automated HPLC Method Development". The focus of his presentation will be Johnson & Johnson's work in developing an automated method development system and how they deal with the resulting data interpretation and management. The final presentation in this session will be delivered by Dr Adrian Clarke (AstraZeneca, UK)<sup>[11]</sup> with a presentation titled "Holistic LC strategies, from UHPLC to HPLC and back". The presentation is particularly relevant at this time, with many companies juggling with the choice of developing methods that are easily transferred to internal and external partner groups with well established HPLC

technology, or developing methods with intrinsically better properties (speed, sensitivity and resolution) through UHPLC.

In the afternoon, the second invited lecturer session will reflect on 'Quality by Design' (QbD). This is an area of increasing interest in the pharmaceutical industry and has its history in a manufacturing context. The focus of analytical method QbD is on integrating method robustness up-front during the method development process rather than testing the robustness of the whole method through validation after the final iteration is generated. This is an area on which the US Food and Drug Administration (FDA) are placing more onus and in the UK there is a cross-pharmaceutical company group working on this concept. The session will be opened by Nigel Howes (GSK, UK) who will give a practically focussed discussion of QbD HPLC method development in GSK at their Stevenage site. The title for his presentation is "Application of Quality by Design to Analytical".

The final session of the symposium will focus on the utility of stationary phases for manipulating analyte selectivity. Maarten De Beer from Professor Pat Sandra's group (University of Gent, Belgium) will discuss his research on gradient phase optimised liquid chromatography (POPLC). Whereas traditionally POPLC has required isocratic conditions to be used, Maarten will discuss his development of an algorithm to enable the POPLC concept to be used with gradient conditions and demonstrate its application with examples<sup>[12]</sup>. The closing lecture will be given by the eminent Professor Eric Lesellier from the University of Orleans in France. He will be reviewing his research on comparing stationary phase selectivity in Supercritical Fluid Chromatography (SFC)<sup>[13-15]</sup> on which he is a world-leading authority. His lecture will conclude what we believe will be a very interesting and informative meeting.

We still have one or two invited speaker slots to fill, but we are in contact with a number of high-profile speakers and will post further agenda updates on the Chromatographic Society website (<http://www.chromsoc.com/ChromsocEvents.aspx>).

On both days there will be sessions dedicated to vendor presentations which will mesh with the invited speaker programme on each day. In these sessions the vendors will provide insight into their current product portfolios and the application of their technologies to small molecule separations. These presentations are always scientifically strong and form a key aspect of the Spring Symposium.



The Chromatographic Society's Annual General Meeting will also be held over the lunchtime of the second day of the symposium. All members of the Chromatographic Society are strongly urged to attend this and contribute their thoughts on the Society's direction.

A limited number of bursaries are being provided by the Chromatographic Society for students wishing to attend this meeting. Requests for these bursaries should be directed to Dr Amjad Khan ([Amjad.Khan@astrazeneca.com](mailto:Amjad.Khan@astrazeneca.com)). Registration for this meeting is open now and can be accessed through the Chromatographic Society website (<http://www.chromsoc.com/ChromsocEvents.aspx>). All enquiries for the meeting should be directed to our secretariat Meeting Makers ([chromsoc@meetingmakers.co.uk](mailto:chromsoc@meetingmakers.co.uk)).

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## Agenda

Note preliminary agenda: Speakers, topic areas or presentation times may be subject to change

### Day 1

- 12:00 Registration, exhibition and light buffet lunch
- 13:00 Welcome address – Alan Handley (President of the Chromatographic Society)
- Session 1: State-of –the art in method development**
- 13:15 Keynote Lecture 1: **Dr Chris Welch** (Merck, USA) - Chromatographic Method Development in Support of Pharmaceutical Process Research
- 14:00 Keynote Lecture 2: **Dr John Dolan** (LC Resources, USA) - Identifying Equivalent and Orthogonal Columns for HPLC Method Development.
- Scientific Vendor Presentations 1
- 14:40 Gold sponsor seminar: **Agilent Technologies**
- 15:20 Vendor 2: TBA
- 15:40 Vendor 3: TBA
- 16:00 Tea Break
- Session 2: Analytical Strategies for Genotoxic Impurities**
- 16:30 Lecture 1: **Dr Remco Stol** (Schering Plough, The Netherlands) – Analytical methodologies for detection and quantitation of genotoxic impurities
- 17:00 Lecture 2: **Dr Tom van Wijk** (Solvay, The Netherlands) - Strategies for Genotoxic Analysis
- 17:30 Close of Day 1

### Day 2

- 9:00 Arrival and coffee
- Session 3: Industrial perspectives**
- 9:30 Lecture 3: **Dr Roman Szucs** (Pfizer, UK) - Is in-silico chromatographic method development - a myth or a real possibility?
- 10:00 Lecture 4: **Dr Rudy Sneyers** (Johnson & Johnson, Belgium) – COSMOS... A Science- based Strategy in Automated HPLC Method Development
- 10:30 Lecture 5: **Dr Adrian Clarke** (AZ, UK) - Holistic LC strategies, from UHPLC to HPLC and back
- 11:00 Tea Break
- Scientific Vendor Presentations 2
- 11:40 Vendor 4: TBA
- 12:00 Vendor 5: TBA
- 12:20 Vendor 6: TBA
- 12:40 Vendor 7: TBA
- 13:00 Lunch & Exhibition
- 13:30 AGM
- Session 4: Quality by Design for Analytical Methods**
- 14:30 Lecture 6: **Nigel Howes** (GSK, UK) - Application of Quality by Design to Analytical
- 15:00 Lecture 7: TBC
- 15:30 Tea break
- Session 5: Stationary phase selectivity**
- 15:45 Lecture 8: **Maarten De Beer** (University of Gent, Belgium) - Stationary-Phase Optimised Selectivity Liquid Chromatography: Development of a Linear Gradient Prediction Algorithm and applications
- 16:15 Lecture 9: **Prof. Eric Lesellier** (University of Orleans, France) – Super Critical fluid Chromatography for small molecule separation: an expanding universe
- 16:45 Closing Address: **Dr Alan Handley**

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