Mission Report[1]

Mission Objective: To give an oral and a poster presentation at the AT Europe 2015 – Analytical technologies in the biopharmaceutical industry.

Date and Place: 18-20 March 2015, Berlin, Germany.

Name of Mission Performer(s)	Mission No.	Unit Name and No.
Guy Auclair	OM-15-1010305	SID-D.02
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Other participants from JRC/EC	Institute/DG	Unit

Other External Participants	Organisation

Summary of the Mission[2]: From the 18th to the 20th of March, the 1st Symposium on analytical technologies in the biopharmaceutical industry (AT Europe 2015) took place in Berlin (Germany). The conference, organised by the California Separation Society (CASSS), is a European spin-off of two US-based conferences organised by CASSS, namely the symposium on practical applications of capillary electrophoresis for the analysis of proteins, nucleotides and small molecules (CE Pharm) and the symposium on practical applications of mass spectrometry in the biotechnology industry (Mass Spec).

The symposium was split in seven different sessions:
- Interface development and quality control
- New trends in capillary electrophoresis
- Method development and quality by design
- Post-translational modifications
- New trends in mass spectrometry
- Capillary electrophoresis-mass spectrometry
- Regulatory.

On top of that, three technical seminars were organised by vendors (Sciex Separations, Genedata GmbH and Bruker Daltonik) on their latest developments and one round-table workshop on specific issues (see the joined document for the topics – GA attended the Tables 3 and 10, VT the tables 2 and 4).

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[1] To be completed within 7 working days of returning from the mission;
[2] Maximum 2 pages;
[3] IRMM Unit Head(s), Team Leader(s), Direct Supervisor

Finally, poster sessions were organised at each breaks during the conference.

Implication/Impact: GA gave an oral presentation on "Application of capillary electrophoresis for the standardisation of measurements of protein biomarkers for in vitro diagnostics" was presented in the new trends in capillary electrophoresis session. It gave examples on the use of different modes of capillary electrophoresis (CE) in the purity assessment of our primary calibrators used in the value assignment of our matrix materials. Positive feedbacks were received from the audience regarding the strategy used and new ideas were also shared on how to improve the outcome of such measurements.
VT presented the poster "Affinity Capillary Electrophoresis to discriminate pentameric and monomeric C-reactive Protein (CRP)" in the New trends in CE technology section.
The poster received really enthusiastic feed-backs from the participants attending the conference and would like to keep contact with VT to develop such approach and/or to collaborate to master this methodology and be scientifically at the forefront. One of the conference organisers stressed that she would like VT to give an oral presentation in US to the future CE Pharm congress on the method developed.

Interesting examples on structural characterisation of biologics (monoclonal antibodies, vaccines) with either capillary electrophoresis and liquid chromatography-mass spectrometry or even hyphenated CE-MS were presented. A lot of discussions were highlighting the lack of suitable reference materials to really assess the trueness of the methods used. It was also mentioned that NIST may be in the process of preparing a reference material for monoclonal antibodies with certified variants. The vaccine application may also bring potential information for the future development of a reference material for viruses.

The presentation from SCIEX was split in three parts introducing a successful application of CE for the measurement of N-glycan using magnetic beads then a quick introduction of the CESI technology to improve the application of CE-MS measurements. Finally, Milla Neffling presented the SWATH Acquisition solution allowing the quantification of several proteins in complex mixtures. Examples presented were showing very good sensitivity for two proteins (C-reactive protein (CRP) and beta-2-microglobulin (B2M)) on which EC-JRC-IRMM has currently projects on-going. The possibility of exploring the extent of this application on some of our matrix materials could be investigated.

Follow up Actions/Actors: GA to follow up with Sciex on measurements of B2M and CRP in complex matrices with mass spectrometry based applications.
Continue monitoring the development of CE-based methodologies for IgG in solution and vaccines to support the development of future reference materials.

VT will optimise the CE method developed and interact with Prof. Wätzig, Dr Neusüß and Dr Haselberg respectively to perfectionalise affinity capillary electrophoresis methods. Follow up on new developments regarding post translational-modifications (methods, accessories...) for potential optimisation of the method already developed at IRMM by VT and AMP. Follow up of mass spectrometry methods for assessing protein impurities and protein quantification.

Copy[3]: H. Emons, S. Trapmann

Signature of Mission Performer(s)	**Date**
.....	30/03/2015
.....	30/03/2015
.....	.....

Approved: ..... **Date:** 31/03/15
(Name and Signature of Unit Head or Director)