Programme

Day One- 18 May 2026

09:30-10:15 Coffee and registration

Session 1: Challenges and Opportunities of ALCM: State of the Nation for Analytical Life Cycle
10:15-10:25 Introduction and Welcome
Adrian Clarke (on behalf of ChromSoc & RSC Separation Science Group), Novartis Pharma AG, Basel, Switzerland
10:25-11:05 ICH Q2 (R2) and Q14: Challenges and Opportunities and Where it May Lead Us
Jean-Francois Diereck, GSK, Belgium
11:05-11:35 AQbD-Driven Ion Pairing RPLC Method Development for Oligonucleotide Impurity Characterization: A Risk-Based Approach under ICH Q14
Amanda Guiraldelli Mahr, RIC, Belgium
11:35-12:15 A Platform Approach to Charge Variant Analysis of Monoclonal Antibodies
Sandra Furlanetto, University of Firenze, Italy
12:15-12:30 TBC: Flash Poster Session or Vendor slot

12:30-14:00 Lunch, exhibition and posters

Session 2: Application of State-of-the-Art Analytical Life Cycle Approaches
14:00-14:30 Performance-based Definition of Analytical Platform Using and Enhanced Performance-Based Approaches.
Nina Trost, Novartis Pharmaceuticals, Slovenia
14:30-15:00 Applied AQbD from A to Z – Pragmatic ICH Q14 Case Study Using Capillary Electrophoresis for Virus Quantification
Ewoud van Tricht, Kantisto, The Netherlands
15:00-15:30 Analytical Method Lifecycle as part of Control Strategy
Maire Welham, AstraZeneca R&D, UK

15:30-16:00 Coffee, exhibition and posters

Session 3: Advances in Analytical Life Cycle Technologies and Philosophies
16:00-16:40 QbD - a Philosophy not a Template & One For All: a SFC-MS/MS Platform Method for the Analysis of Multiple Nitrosamines in Accordance with the ICH Guidelines
Mijo Stanic & Andreas Zappe, Chromicent, Germany
16:40-17:00 Advancing Robustness Verification for Validated and Compendial Methods on the Alliance iS HPLC System: Practical Integration of ICH Q14 and Lifecycle Risk Principles
Andrea Gheduzzi, Waters, UK
17:00-17:20 From Experience-Based HPLC to a Systematic, Controlled Method Lifecycle as part of ICH Q14 with ChromSwordAuto
Arthur Kalimulin, ChromSword, Austria

17:20 -19:00 Networking Event & Poster Viewing

Day Two - 19 May 2026

09:00-09:30 Posters and Coffee

Session 4: Smart Analytical Life Cycle Strategies

09:30-10:00 GC Analytical Platform for the Analysis of Residual Solvents - AQbD/Analytical Lifecycle Approaches
Mikael Nilsson, Cambrex, Sweden

10:00-10:20 Designing Smarter Methods: Vacuum UltraViolet Detection from Early Insight to Life Cycle Control
Richard Ladd, VUV Analytics / UVision, UK

10:20-10:40 Software-aided Method Development and Optimisation for SFC Separations
Gesa Schad, Shimadzu European Group, Germany

10:40-11:00 Strategies for the Prevention of False Positives and False Negatives in Nitrosamine Testing
Nathanael Page, Resolian, UK

11:00-11:30 Coffee, exhibition and posters

Session 5: Digital Tools and Approaches in the Analytical Life Cycle

11:30-12:00 Separation Quality Factor: A Comprehensive Tool for Ranking, Modelling, and Optimizing Gradient Separations
Szabolcs Fekete, Waters AS, Switzerland

12:00-12:30 From Instruments to Insight: Analytics in the Digital, Automated Lab
Christian Haas, Agilent, Germany

12:30-13:00 Autonomous Optimisation of Small-Molecule and Oligonucleotide Separations via Bayesian Machine Learning Algorithms
Matthew Notley & Edward Ahearne, AstraZeneca R&D, UK

13:00-14:30 Lunch, exhibition and posters (including the Chromatography Society AGM)

Session 6: Further Advances and Opportunities: Digitalisation, Scientific Practices and Sustainability

14:30-15:00 Digitalising the Analytical Method Lifecycle: an Industrial Use Case
Lewis Shipp, QbDVision, UK and Stephanie Toulot, Novartis Pharma AG, Switzerland

15:00-15:30 Retention Prediction for Green Methods
Ilaria Neri, University of Cork, Ireland

15:30-16:00 Good Compliance, Good Science? Why We Need to Talk About Good Scientific Practice in ALCM
Wiebke Holkenjans, Bayer AG, Germany

16:00-16:50 Panel Discussion: The challenges and opportunities in ALCM

16:50-17:00 Close
Lisa Hinchliffe (on behalf of JPAG), Independent Regulatory CMC Consultant, UK

Abstracts

Edward Ahearne - AstraZeneca
see Matt Notley

Sandra Furlanetto - University of Firenze, Italy
In the biopharmaceutical field, ensuring the safety and efficacy of a product represents a complex analytical challenge. Several Critical Quality Attributes must be taken into consideration, and one or more Analytical Procedures (APs) must be developed for each of them. For this reason, the development of horizontal methods, as proposed by the European Pharmacopoeia

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Dr Richard Ladd - RML Consulting
This presentation outlines the evolution of pharmaceutical regulations and the role of the International Council for Harmonisation, highlighting how ICH Q14 enables flexible, science- and risk-based method development.
Vacuum ultraviolet (VUV) detection for GC and LC is presented as a smarter analytical choice, offering enhanced sensitivity and broad-spectrum selectivity via unique spectral fingerprints. These capabilities improve analyte understanding, simplify method design, and support robust, lifecycle-ready control strategies aligned with ICH Q14 principles.

Stephanie Toulot - Novartis

As regulatory expectations evolve under ICH Q14 and USP <1220>, Analytical Procedure Lifecycle Management (APLM) must shift from document-based workflows to data-centric, knowledge-driven approaches. However, many analytical environments still rely on fragmented systems and manual processes, limiting efficiency, traceability, and compliance.
This presentation explores Digital Analytical Methods (DAMs) as a key enabler of this transformation, supported by digital CMC platforms such as QbDVision. By structuring analytical methods into machine-readable, interconnected data, DAMs—combined with QbDVision's unified knowledge framework—enable seamless traceability of analytical intent, parameters, and performance across the lifecycle.
A real-world case study at Novartis demonstrates the transition from a sequential, document-centric model to an integrated digital ecosystem supported by this eCMC platform. This approach enables automated data capture, streamlined workflows, and centralized knowledge management aligned with the Analytical Target Profile (ATP), risk assessment, and validation strategy.
Together, DAMs in QbDVision enable faster technology transfer, improved data integrity, and more robust, compliant, and future-ready analytical lifecycle management.

Dr Jean-françois Dierick - GSK
The new version of ICH Q2 (R2) "Validation of Analytical Procedure" and the new ICH Q14 "Analytical Procedure Development" have been approved recently. Beside modernizing the text and addressing topics in the mood of time (Real-Time-Release, multivariate models, …), these two guidelines bring the concepts of Analytical Quality by Design through the description of an "enhanced approach". Opportunities like reuse of development data and abbreviated validation of platform procedures are addressed but not in great details, and probably to an extent that does not allow the immediate realization of the game changing

potential of the application of AQbD concepts to (platform) analytical procedures development, validation and lifecycle.

The objective of the presentation is to share a vision where the concepts from the enhanced approach (ATP, risk management, knowledge management, validation, assay control

strategy, change management) can accelerate the availability of more robust validated (platform) analytical procedures, can facilitate the extension of usage to new products, and contribute to the reduction of product development lead time.

The positioning will be knowingly progressive in order to stretch towards the most ambitious vision and to envisage together the long-range benefits that are possible but not promised and, in any case, depend on how we will implement ICH Q2 and Q14.

Szabolcs Fekete - Waters AS

Traditional chromatographic performance metrics, such as plate number, selectivity, and resolution, describe only isolated aspects of separation quality and often fail to capture the overall performance of complex gradient separations. In this contribution, we introduce the Separation Quality Factor (SQF), a comprehensive, dimensionless descriptor that integrates multiple normalized metrics, including kinetic efficiency, peak symmetry, peak distribution uniformity, elution window utilization, and critical peak order. By combining these independent factors using a geometric mean, SQF provides a single quantitative value between 0 and 1 that highlights the weakest link in a separation while enabling objective ranking and comparison of methods and columns.
The applicability of SQF is demonstrated through practical case studies in pharmaceutical impurity profiling, including systematic method screening, multidimensional optimization, and column comparison. Results show that SQF serves as an effective global response function, guiding method development beyond conventional resolution based criteria. Furthermore, SQF can be normalized to analysis time and implemented directly within chromatographic data systems, enabling automated and user friendly separation quality assessment. Overall, SQF represents a robust and versatile tool for rational method optimization in both research and regulated environments.

Andrea Gheduzzi - Waters

This session demonstrates a practical framework for verifying robustness when implementing validated or compendial methods on the Alliance iS HPLC system, showing how its built in error reduction features and seamless integration with Empower CDS strengthen routine analytical reliability. By applying ICH Q14 concepts within a risk based lifecycle approach, it highlights how laboratories can enhance method control, reduce variability, and ensure consistent performance during method transfer and ongoing execution.

Amanda Guiraldelli Mahr - RIC

This presentation will illustrate the practical application of the ICH Q14 enhanced approach for analytical procedure development through the integration of risk assessment and multivariate experimental strategies. Key risk assessment tools will be highlighted, including the use of Design of Experiments (DoE) to systematically evaluate critical method parameters and their interactions. Additional strategies, such as prediction modeling, desirability functions for multi-response optimization across impurity classes, and prediction intervals, will be presented in the context of in-silico robustness assessment, enabling a deeper understanding of sources of variability. The concept of a Method Operable Design

Region (MODR), as described in ICH Q14 and USP <1220>, will be discussed, including the tools and approaches used to define it, alongside the development of appropriate control strategies such as system suitability tests and acceptance criteria. In summary, this presentation showcases the design of a
robust, knowledge-based foundation to support subsequent stages of the analytical procedure lifecycle.

Christian Haas - Agilent Technologies

As laboratories continue to advance through automation and digitalization, analytical instruments are becoming a key interface between experimental reality and data-driven decision-making. The quality, structure, and accessibility of the data generated at this interface are critical for enabling robust downstream analytics, including machine learning-based approaches.
This lecture will highlight how advanced software can be integrated with LC hardware and external automated workflows to support the reliable generation of high-quality chromatographic data in increasingly automated laboratory environments. Building on this foundation, the presentation will showcase a prototype for automated LC gradient optimization in OpenLab CDS, demonstrating how machine learning can support more systematic and efficient method development.
The lecture will conclude with an outlook on the evolving role of digital tools in the analytical method lifecycle and will emphasize the importance of close collaboration between instrument vendors and laboratory users in translating technical innovation into practical analytical value.

Wiebke Holkenjans - Bayer Aktiengesellschaft

Analytical Quality by Design (AQbD) and Analytical Lifecycle Management (ALCM) are built on deep scientific understanding. In practice, however, the conversation often collapses into a compliance-driven discussion. At the same time, development data generated outside a formal GMP environment increasingly inform CMC narratives, control strategy decisions, and lifecycle changes. This raises a recurring question: what makes non-GMP analytical data defensible for regulatory use, and how do we ensure rigor without turning development into "GMP by default"?
This presentation explores Good Scientific Practice (GSP) as the connective layer between explorative non-GMP and formal GMP activities, introduces a purpose- and risk-based framework for "regulatory use," and proposes minimum requirements for defensible GSP data. Rather than presenting a fixed operating model, the talk is designed to open a discussion: how can we preserve scientific flexibility and innovation while building regulatory confidence across the analytical lifecycle?

Arturs Kalimulins - ChromSword

HPLC method development is still driven by analyst experience, leading to experience-based workflows, limited reproducibility, and inefficient use of instrumentation and time. With the introduction of ICH Q14 guidelines, the industry has begun to focus more on a systematic, science- and risk-based approach to analytical procedure development throughout the lifecycle.
However, current HPLC method development processes are primarily supported by chromatography data systems (CDS) that execute experiments but do not guide structured decision-making or enforce consistent workflows.
This presentation outlines a systematic HPLC method lifecycle framework aligned with ICH Q14, integrating screening, model-based development, impurity profiling, robustness studies,

and validation into a unified process. The approach is demonstrated using the ChromSwordAuto software package to combine automation, design of experiments (DoE), and AI-supported mechanistic modelling.
By using mechanistic retention models enhanced with AI-driven optimisation, ChromSwordAuto enables more effective HPLC method development, increases speed and efficiency, reduces the risk of human error, and leads to clear and efficient decision-making. This transforms method development from an experience-based activity into a systematic, controlled workflow.
The presentation will cover how digitalisation and intelligent modelling can support the practical implementation of ICH Q14 to enable more robust, reproducible, and lifecycle-oriented analytical methods in modern pharmaceutical development.

Ilaria Neri - University of Cork
As the complexity of analytical samples grows, traditional "trial-and-error" chromatography becomes a bottleneck in the laboratory. Quantitative Structure-Retention Relationship (QSRR) modelling offers a predictive framework to accelerate drug discovery, development, and manufacturing. This tutorial style mini session outlines the roadmap for building a robust QSRR model. By following a systematic framework, it will analyse the crucial phases of the project, bridging theoretical principles with experimental practice and covering the following topics:
• Dataset design and curation: the success of any QSRR model depends on data quality. We discuss typical selection criteria with examples used in our current studies to balance chemical diversity with structural and real-world relevance.
• Experimental data collection and pre-processing: we will outline the approaches typically used to prepare experimental data before any modelling strategies can be applied including splitting strategies, scaling and feature selection.
• Modeling strategies: here we will overview the choices available across physicochemical, statistical or hybrid approaches.:
• Model Refining, Tuning and Training: here we will describe the workflow and options for algorithm selection, hyperparameter tuning and final training.

Dr Mikael Nilsson - Cambrex Karlskoga
Objectives

As per ICH Q2 a platform analytical procedure is defined as: “An analytical procedure that is suitable to test quality attributes of different products without significant change to its operational conditions, system suitability and reporting structure. This type of analytical procedure can be used to analyze molecules that are sufficiently alike with respect to the attributes that the platform analytical procedure is intended to measure.” (1). A similar definition is provided in USP <1220> (2).
In this work, 18 residual solvents were selected and an analytical method was developed and optimized based on the method operable design region (MODR) approach and validated as a platform analytical procedure (PAP. Method development was driven by a clear and concise analytical target profile (ATP) (3), ensuring that performance characteristics were aligned with quality attributes.

Materials and methods

A retrospective evaluation of solvents used in active pharmaceutical ingredient (API) synthesis over the past 15 years was performed to identify the most frequently applied compounds. Anticipated future solvent requirements were addressed through consultation

with subject matter experts in chemical route development. Based on this lifecycle-oriented assessment, 18 solvents were defined within the analytical target profile (ATP). Chromatographic parameters, including column dimensions, oven temperature program, and carrier gas flow, were systematically investigated. A single headspace GC method capable of separating and quantifying all selected solvents, including critical pairs, was developed. Method development followed a quality-by-design approach in accordance with ICH Q14, using structured experimentation to establish a method design space for headspace conditions. A linear regression model describing headspace response was constructed and verified, demonstrating predictable analyte response within the design space and supporting robustness in line with ICH Q2 performance expectations.

Results

- Successfully developed and validated a generic HS-GC method for the determination of 18 solvents.
- Resolution ?1.5; range at least 20-200% of ICH limit; tailing 0.8 to 2.0
- A model, based on a quality by design approach was successfully developed for the HS section.
- A working range for oven temperature, equilibration time, vial pressure and vial filling were systematically evaluated and confirmed
- Any changes made to any of these settings within the tested design space do not require a new validation.
- Development and validation efforts required for applying the PAP to a product is significantly reduced compared to developing a method from scratch

Conclusions
Overall, this work demonstrates that platform analytical procedures can be effectively developed and implemented while making use of the creation of MODR and ensuring compliance with regulatory requirements.
This work lays the foundation and provides a structured approach for the creation of analytical platforms, removing some of the uncertainty and facilitating the broader pharmaceutical industry adoption

References
(1) ICH Q2(R2) guideline on validation of analytical procedures, 2024. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q2r2-guideline-validation-analytical-procedures-step-5-revision-1_en.pdf (accessed June 13, 2025).
(2) USP,?1220? Analytical Procedure Life Cycle, 2022
(3) ICH, ICH Q14 Guideline on analytical procedure development, 2024. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q14-guideline-analytical-procedure-development-step-5_en.pdf (accessed June 13, 2025).

Matthew Notley - AstraZeneca

Developing chromatographic purity methods is a major analytical resource spend in pharmaceutical development, particularly under accelerated timelines. Automating method development offers substantial efficiency gains and is therefore a strategic priority. During route design and process optimisation, rapid substrate turnover and evolving impurity profiles often necessitate repeated method-development cycles; when generic methods are insufficient, teams typically resort to one?factor?at?a?time adjustments. In later phases and for release testing, retention modelling or design of experiments are commonly used to identify optimal conditions. Both stages demand extensive analyst time, underscoring the

case for automation.

We evaluated a closed?loop, operator?free Bayesian Automated Method Optimiser (BAMO)—a machine?learning workflow that autonomously designs, executes, and analyses chromatographic experiments on live instruments. Treating the chromatographic system as a black box, BAMO iteratively selects conditions to maximise predefined critical quality attributes. We applied this approach across diverse separation challenges, development stages, and chromatographic modalities, and compared its speed, resource utilisation, and method quality with current practices.

Nathanael Page - Resolian

Nitrosamines are potent genotoxic impurities, and their assessment at trace levels presents significant analytical challenges. Both false positive and false negative results can have substantial regulatory, scientific, and financial consequences.

This presentation explores practical strategies to minimise these risks throughout the analytical workflow for nitrosamine testing. Key sources of false positives are examined, including sample handling, preparation, storage, and analytical conditions that can promote artefactual nitrosamine formation or isobaric interferences. Mitigation approaches are discussed using a “nitrosamine triangle” framework, highlighting control of amine sources, nitrite, and heat or acidic conditions.

The presentation also addresses false negatives, focusing on the role of liquid chromatography–high resolution accurate mass spectrometry (LC HRAMS) in enhancing confidence in identification and sensitivity. The impact of instrument design, ionisation behaviour, source and ion guide parameters, and acquisition strategies is demonstrated using real world examples.

Gesa Schad - Shimadzu European Group

In the evolving landscape of analytical chemistry, Supercritical Fluid Chromatography (SFC) is emerging as a powerful technique that combines efficiency with versatility in compound separation. At the same time, chromatographic methods are increasingly expected to be designed with their entire life cycle in mind, from early development to routine use and the possibility of future improvement. While computer-assisted method development is common in HPLC, differences in SFC retention behavior have until recently limited its broader use in this area.

This presentation will show how using method development software that applies Analytical Quality by Design (AQbD) principles by using Design of Experiments (DoE) to streamline SFC method screening and optimization. Using standard mixtures as model samples, we will demonstrate how this approach defines robust design spaces, improves method reliability, and supports easier validation and transfer. Overall, we will highlight how informed, data-driven SFC method development enhances control and performance across the full method life cycle.

Mijo Stanic - Chromicent GmbH

This presentation demonstrates how Chromicent has spent the last 15 years establishing and advancing the principles of DoE, QbD, and Analytical Method Lifecycle Management within its operations to address client challenges and needs. For Chromicent, these concepts represent a matter of philosophy rather than a mere template to be mechanically executed, as they can be seamlessly integrated into a wide range of challenges - including, for example, LC, SFC, sample preparation, dissolution testing, nitrosamine analysis, and others.

Nina Trost - Novartis Pharmaceuticals

This presentation proposes a performance-based approach to analytical procedure development and lifecycle management, built on the principle that parameters may change, but procedure performance must remain constant. Central to this concept is the definition of a technology-specific “performance corridor,” derived from the Analytical Target Profile (ATP), which defines the allowable analytical uncertainty required for reliable decisions.
Using company data, it is demonstrated that different method configurations can deliver consistent analytical performance, supporting the implementation of performance-based analytical platform approaches.

Dr Ewoud Van Tricht - Kantisto

A complete AQbD implementation following ICH Q14, from Analytical Target Profile to lifecycle management, demonstrated through a CZE method for adenovirus quantification. The approach successfully replaced qPCR, reducing time-to-result from several days to under one hour.

Maire Welham - AstraZeneca

This presentation provides an overview of AstraZeneca’s approach to Analytical Method Lifecycle Management (AML), highlighting how the company has established governance, business processes, and specialist networks to embed lifecycle thinking across the analytical landscape.
A brief case study will also be presented describing application of AML concepts to development of a commercial assay control strategy for an antisense oligonucleotide. Assay performance was impacted by cumulative measurement uncertainty across a multi-site analytical footprint. Through risk-based performance monitoring and global method standardisation, the team improved understanding of method variability and used these insights to support simplification of the control strategy.

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1) Implementation of a platform analytical procedure for residual solvents testing of two APIs, using elements of the enhanced approach to method development.

Anna Ander, Katarina Hegestad, Irina Castaños, Mikael Nilsson
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Objectives/Introduction
In previous work, a generic headspace gas chromatographic (HS-GC) was developed and validated as a platform analytical procedure (PAP) for determination of residual solvents, with a clear line of sight to smooth filing of a product specific method built upon the generic PAP (1). A framework for developing and validating product specific methods was also provided. The approach combines elements of the enhanced approach to method development laid out in ICH Q14 (2) with the possibility to reduce validation efforts for platform procedures. ICH Q2 (3) says that “when an established platform analytical procedure is used for a new purpose, validation testing can be abbreviated, if scientifically justified”.

In this work, the generic PAP and the framework for implementation of it was applied in the development of product specific methods for residual solvents testing for two APIs (referred to as API-1 and API-2). The residual solvents of interest, acetone and toluene for API-1 and toluene for API-2, are included in the PAP.

Materials and methods
The generic PAP is a HS-GC method capable of resolving and quantifying 18 common solvents. A method operable design region (MODR) was established for the HS settings to gain increased method knowledge and to provide flexibility for future applications (1).

In this work, the proposed strategy for implementation of the generic PAP was applied. The analytical conditions were set as defined in the generic PAP, including the recommended nominal settings for the HS part and the suggested sample preparation procedure. The same conditions were used for both APIs.

Results
An analytical target profile (ATP) was defined for each API. The acceptance criteria for each performance characteristics was compatible with the ATP for the generic PAP. The risk assessment elaborated for the generic PAP (1) was considered sufficient for the analysis of API-1 and API-2, with no additional risks identified.

The experimental work was focused on product behavior and assessing the suitability of the PAP for the two APIs studied. The ATP acceptance criteria for specificity, accuracy, repeatability, and sample solution stability were fulfilled.

For the generic PAP, a MODR was established for the following HS parameters: HS oven temperature, HS vial equilibration time, volume of liquid in the vial, and vial pressure. For the product specific methods, three of these parameters (HS oven temperature, HS vial equilibration time, and vial pressure) were varied in an experimental design (full factorial, with three center points) to evaluate the impact on specificity, accuracy and sensitivity for acetone and toluene in presence of product matrix. The study showed that the ATP criteria were consistently met within the evaluated parts of the design space, meaning that a MODR can be described in the filing documentation for the APIs and that the methods are robust under normal operating conditions. The study also confirms the useability of the PAP for products with different properties.

Before the product specific methods can be used for routine quality control, they must be formally validated with respect to specificity, repeatability and intermediate precision, accuracy, and range. These validation activities are an extension of the validation of the generic PAP.

Conclusions
The work presented shows how a well-designed PAP can be easily implemented for API testing. The method performance across selected parts of the MODR, originally established for the generic PAP, was assessed for the product specific methods. The study showed that the ATP criteria were consistently met within the evaluated parts of the design space. The flexibility of a MODR can thus be incorporated into the product specific method documentation.

References
(1) Dang, N., Ander, A., Bohlin, M., Neto, R., & Nilsson, M. (2026). Platform analytical procedure for the analysis of residual solvents in active pharmaceutical ingredients by headspace-gas chromatography – A use case of implementation. Journal of Pharmaceutical and Biomedical Analysis, 269. https://doi.org/10.1016/j.jpba.2025.117243
(2) ICH Q14 Guideline on analytical procedure development, 2024. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q14-guideline-analytical-pr

ocedure-development-step-5_en.pdf (accessed June 13, 2025).
(3) ICH Q2(R2) guideline on validation of analytical procedures, 2024. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q2r2-guideline-validation-analytical-procedures-step-5-revision-1_en.pdf (accessed June 13, 2025).

2) Concept for software-based method development related to the enhanced approach for small molecules in pharmaceutical development

CMCA-NCE Analytical Development: Alena Ludat, Jan Tobias Ritterhoff
CMC Analytics: Wiebke Holkenjans
Bayer AG, Pharmaceuticals, Friedrich-Ebert-Str. 217-333, 42117 Wuppertal, Germany

The determination of the quality of drug substance and drug product is a critical step in the development of new chemical entities for which analytical test procedures for release and stability testing are needed. Therefore, the development of these analytical methods is a critical step in pharmaceutical development.
The use of quality by design (QbD) principles as described in ICH Q14 results in the possibility of performing much more efficient development of new analytical methods which also generates a deeper understanding of the method performance and of different impact factors. This can serve as a basis for the analytical control strategy and facilitate life cycle management for analytical procedures.
The challenge in using QbD principles and gaining a deep understanding of a new analytical method results from the high number of experiments and the interpretation of the corresponding amount of generated data.
To address this challenge, we implemented a step-by-step concept involving data aggregation, method screening, method optimization and robustness experiments using different software dedicated to analytical method development. This software supports by generating design of experiments (DoE) based on specific chromatographic conditions. In addition, it offers the opportunity to model certain parameters to gain information about the impact on the chromatographic performance using existing experimental data.

3) An integrated chiral screening approach – optimising workflows across three modes (RP-HPLC, SFC and NP-HPLC)

Lucy Smith1

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Objectives

Enantioseparation has become a topic of increasing interest in the pharmaceutical industry, with around 50% of marketed drugs being chiral.1 Therefore, accurate analysis is essential for regulatory compliance. High-performance liquid chromatography (HPLC) is the primary tool for enantioseparation since its ability to separate enantiomers via chiral stationary phase interactions is unmatched. However, in recent years the use of supercritical fluid chromatography (SFC) has become a topic of increasing interest given its complementary selectivity, faster column equilibration times and lower solvent consumption benefits.

Chiral method development is often laborious due to its unpredictability, which can be overcome by designing a systematic screening system. This integrated screening approach

aimed to devise quantitative guidance on mobile phase compositional adjustments, and subsequent instrumental conditions, essential for streamlining chiral method development. With the overall aim to produce a fully effective screen, enabling junior analysts to go from having no prior knowledge of a compound to a validated method suitable for GMP analysis, including complex mixtures of chiral centres.

Methods

The project was conducted using a reverse and normal phase Agilent 1260 Infinity II HPLC instrument and Agilent 1260 Infinity III SFC-UV instrument. Each instrument was equipped with a G7116B multicolumn thermostat and G1170A valve drive from the Agilent 1290 Infinity II range. Polysaccharide-based columns (150 × 4.6 mm, 3 ?m) were selected for their diverse interaction mechanisms, including carbamate hydrogen bonding, ?–? stacking, and steric effects from the helical polymer structure. Initial pre-screening established suitable pH, additives, and modifier compositions, enabling a full screen to identify the optimal column and mobile phase. Subsequent refinement of parameters such as temperature and injection volume could then be identified to further enhance resolution.

Results

In addition to the protocol, an unexpected finding was that both acidic and basic additives should be examined. Complementary selectivity for different stationary phases varied heavily, influenced by both the different ionised states of the API and the modification to the interactions with the polar stationary phases.

Conclusions

Our analysts can now use this structured integrated screening protocol to efficiently develop and optimise chiral methods ready for validation, surpassing typical manufacturers recommendations for chiral screening.

References

1. P. Anaikutti, S. Dhanasekarand, B. Komarasamy, R. Krishnamoorthy, S. Sarkar, N. Senkuttuvan, RSC Advances, 2024, 14, 33429-33448.

4) A Decision-Based GC-FID Workflow for Residual Solvent Analysis

Carla Nassour1, Steven Hunter1

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Objectives

Residual solvents are used during the manufacture or purification of drug substances. As these solvents are not always completely removed by conventional manufacturing processes, testing is required to ensure that residual levels comply with ICH-defined limits to meet patient safety requirements. 1 At Pharmaron, a universal generic residual solvents method was developed that adequately separates most commonly used solvents. In this

work, a structured, decision?based workflow was established to guide method development when deviation from the generic method is required due to analyte, matrix, or performance-related challenges. Implementation of this approach is intended to significantly reduce analytical development time, improve method transferability, and increase laboratory efficiency while reducing solvent waste.

Materials and methods

The generic method was developed using Agilent 8890 GC systems equipped with flame ionisation detection (FID) and DB-624 columns. The final 13-min method was divided into two sections: (1) a method covering 29 solvents using NMP as diluent, and (2) a method covering 21 solvents using MeOH as diluent. These methods were applied across multiple drug substance projects. The workflow was established following a retrospective review of method-related challenges observed across these projects. These observations were used to define a structured workflow incorporating decision points related to diluent selection, stationary phase choice, temperature programme optimisation, analytical range, and instrumental configuration.

Results

The method was designed using standard gas chromatography conditions aligned with regulatory expectations (ICH Q3C), enabling the detection and quantification of commonly encountered residual solvents. The workflow provides a structured framework for assessing generic method suitability, identifying the root cause of method limitations, and defining scientifically justified criteria for further method development. This supports consistent scientific decision-making and reduces trial-and-error-based method changes.

Conclusions

The universal generic residual solvents method provides a reliable solution for routine residual solvent analysis in a drug substance environment; however, the accompanying workflow enables structured, efficient, and reproducible adaptation of the method across diverse drug substance matrices and project requirements.

References

1 ICH Q3C (R9) Guideline on impurities: guideline for residual solvents EMA/CHMP/ICH/82260/2006

5) Achiral HPLC Method Development Workflows.

Jelena Pisaruka1, Shreya Bondili1, Marcin Lisek1, Steven Hunter1

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Objective

Achiral reversed-phase high-performance liquid chromatography (RP-HPLC) methods are routinely developed for assay and related substances analysis of drug substances. However, method development is often performed trial-based, leading to extended timelines. The objective of this work was to establish a four-stage approach for separating active pharmaceutical ingredient (API) from process- and degradation-related impurities. This approach is intended to give methods that are suitably stability-indicating and/or validatable, supporting efficient separation of the API from starting materials, intermediates, and degradation products.

Materials and methods

Achiral RP-HPLC method development was performed using Agilent 1260 HPLC systems equipped with UV diode-array detection (DAD) under gradient elution conditions. A systematic four-stage workflow (pre-screen, sample preparation and screening, post-screen and optimisation) was used to guide key development decisions, including stationary-phase combinations, mobile-phase composition and pH optimisation. The Percepta® (ACD/Labs) software platform was incorporated at the initial stage of the workflow to support prediction of physicochemical properties.

Results

Implementation of the workflow enabled rapid identification of suitable chromatographic conditions to achieve effective separation of the API from synthetic and degradation-related components. Recommended target criteria for resolution, peak tailing and capacity factor were used to guide the decision making after the screen. The workflow reduced development time and supported consistent scientific decision-making across different analytical challenges.

Conclusion

A structured workflow for achiral RP-HPLC method development was successfully developed and applied to drug substance analysis on multiple occasions. This approach improves efficiency while ensuring robust separation of the API from related substances.

References

ACD/Labs. Percepta®, version 2023.2.4; Advanced Chemistry Development, Inc.: Toronto, Canada, 2024.

6) A novel generic approach to the analysis of labile phosphate metabolites of antiviral pro-drugs in dried blood spots using column switching anion-exchange/HILIC-MS/MS

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Objectives

Antiviral nucleoside and nucleotide analogs are critical treatments in the absence of efficient vaccines. Nucleoside reverse transcriptase inhibitors (NRTIs) are prodrugs
that require intracellular conversion to the active triphosphate nucleotide metabolites (NMs) for their pharmacological activity. Quantitation of the active metabolites is fundamental to understanding the relationship between prodrug PK and efficacy.1,2

Analysis of antivirally active nucleotides had previously been reported using time and resource consuming combinations of solid-phase extractions and enzymatic dephosphorylation.2-10

The initial objective of this work was to develop assays for Ribavirin (RBV) phosphates (RBV-Ps) based on a one-step extraction of dried human blood spots (DBS) that could also be used to extract the parent drug.

Materials and methods

Dried human blood spots (DBS) on FTA DMPK-B cards were extracted with a mixture of 25:25:50 acetonitrile-water-pH8 buffer. Labelled uridine phosphates were used as internal standards. The extracts were then injected into a column switching anion-exchange/HILIC LC-MS/MS system. An -NH2 anion exchange guard was used to trap the phosphates which were then separated, after backflushing, on a superficially porous, zwitterionic, HILIC-Z column12 and then quantified using negative ion Electrospray MS/MS.

Results

The method for RBV-Ps passed regulatory acceptance criteria and tests specific to DBS, e.g., position of punch, spot volume. The parent drug was extracted simultaneously, leading to a novel joint assay. This approach was extended to two other antiviral nucleosides, Remdesivir 13-14 and Favipiravir. The assay for the former passed the criteria for a “fit-for-purpose” validation. The assay for the latter is in the process of optimisation. This has been hindered by an unidentified, isobaric, interference which co-elutes with the triphosphate.

?
Separation of RBV-Ps from Isobaric Urd-Ps in reference mixture

Key: MP, DP, TP = mono-, di- and tri-phosphates

Conclusions
A novel column-switching HILIC LC-MS/MS method has been developed and validated for the analysis of antivirally active phosphates of Ribavirin in dried blood spots. It employs a convenient one-step extraction which bypasses the need for SPE and enzymatic dephosphorylation. This approach has been successfully applied to the analysis of nucleotides derived from Remdesivir and Favipiravir.

References
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1. Deville-Bonne, D.;El Amri, C.;Meyer, P.;Chen, Y.;Agrofoglio, L. A.; Janin, J., Human and viral nucleoside/nucleotide kinases involved in antiviral drug activation: Structural and catalytic properties. Antiviral Res. 2010, 86 (1), 101-120.
2. Geraghty, R. J.;Aliota, M. T.; Bonnac, L. F., Broad-spectrum antiviral strategies and

nucleoside analogues. Viruses 2021, 13 (4).
3. Bushman, L. R.;Kiser, J. J.;Rower, J. E.;Klein, B.;Zheng, J. H.;Ray, M. L.; Anderson, P. L., Determination of nucleoside analog mono-, di-, and tri-phosphates in cellular matrix by solid phase extraction and ultra-sensitive LC-MS/MS detection. J. Pharm. Biomed. Anal. 2011, 56 (2), 390-401.
4. 4.Agnesod, D.;De Nicolò, A.;Simiele, M.;Mohamed Abdi, A.;Boglione, L.;Di Perri, G.; D'Avolio, A., Development and validation of a useful UPLC-MS/MS method for quantification of total and phosphorylated-ribavirin in peripheral blood mononuclear cells of HCV+ patients. J. Pharm. Biomed. Anal. 2014, 90, 119-126.
5. Jimmerson, L. C.;Ray, M. L.;Bushman, L. R.;Anderson, P. L.;Klein, B.;Rower, J. E.;Zheng, J. H.; Kiser, J. J., Measurement of intracellular ribavirin mono-, di- and triphosphate using solid phase extraction and LC-MS/MS quantification. J. Chromatogr. B Anal. Technol. Biomed. Life Sci. 2015, 978-979 (C), 163-172.
6. Billat, P. A.; Saint-Marcoux, F., Liquid chromatography–mass spectrometry methods for the intracellular determination of drugs and their metabolites: a focus on antiviral drugs. Anal. Bioanal. Chem. 2017, 409 (25), 5837-5853.
7. Xiao, D.;Ling, K. H. J.;Custodio, J.;Majeed, S. R.; Tarnowski, T., Quantitation of intracellular triphosphate metabolites of antiretroviral agents in peripheral blood mononuclear cells (PBMCs) and corresponding cell count determinations: review of current methods and challenges. Expert Opin. Drug Metab. Toxicol. 2018, 14 (8), 781-802.
8. Fabino Carr, A.;Patel, D. C.;Lopez, D.;Armstrong, D. W.; Ryzhov, V., Comparison of reversed-phase, anion-exchange, and hydrophilic interaction HPLC for the analysis of nucleotides involved in biological enzymatic pathways. J. Liq. Chromatogr. Relat. Technol. 2019, 42 (7-8), 184-193.
9. Gautam, N.;Alamoudi, J. A.;Kumar, S.; Alnouti, Y., Direct and indirect quantification of phosphate metabolites of nucleoside analogs in biological samples. J. Pharm. Biomed. Anal. 2020, 178.
10. Mueller, S. W.;Kiser, T. H.;Morrisette, T.;Zamora, M. R.;Lyu, D. M.; Kiser, J. J., Ribavirin and cellular ribavirin-triphosphate concentrations in blood and bronchoalveolar lavage fluid in two lung transplant patients with respiratory syncytial virus. Transplant Infect. Dis. 2021, 23 (1).
11. Palumbo, D.;Fais, P.;Calì, A.;Lusardi, M.;Bertol, E.; Pascali, J. P., Novel zwitterionic HILIC stationary phase for the determination of ethyl glucuronide in human hair by LC-MS/MS. J. Chromatogr. B Anal. Technol. Biomed. Life Sci. 2018, 1100-1101, 33-38.
12. Hu, W.;Chang, L.;Ke, C.;Xie, Y.;Shen, J.;Tan, B.; Liu, J., Challenges and stepwise fit-for-purpose optimization for bioanalyses of remdesivir metabolites nucleotide monophosphate and triphosphate in mouse tissues using LC–MS/MS. J. Pharm. Biomed. Anal. 2021, 194.
13. Kapoor, S.;Dubey, G.;Khatun, S.; Bharatam, P. V., Remdesivir: Mechanism of Metabolic Conversion from Prodrug to Drug. Curr. Drug Metab. 2022, 23 (1), 73-81.

7) The Rapid Elucidation of Impurities in N-Nitrosatable APIs using Multi Reflecting Time-of-Flight MS with UPLC

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Introduction
Impurities in active pharmaceutical ingredients (APIs) can arise from raw materials,

synthesis, degradation, and storage. Genotoxic impurities such as N-nitrosamines are of particular concern due to the potential significant health risk of regular exposure. Due to the potential mutagenicity of N-nitrosamines, rapid and confident identification of these impurities is key to ensuring patient safety and product availability.

Methods
A range of N-nitrosatable APIs and polymeric excipients were stressed using sodium nitrite and formic acid under elevated temperature conditions. The resulting mixtures were analysed using an ACQUITY™ UPLC I-Class system coupled with a Waters SELECT SERIES MRT instrument. This ultra-high-resolution time-of-flight mass spectrometer (UHRMS) operates with >200,000 FWHM resolving power and was integrated into an automated identification workflow using the waters_connect™ platform and UNIFI scientific information system. MS data were acquired in MSE mode across m/z 50–2400 with LockSpray for mass accuracy correction.

Results
The SELECT SERIES MRT enabled baseline resolution of previously overlapping components, such as N-nitroso and formylated folic acid derivatives. Sub-ppm mass accuracy allowed confident assignment of elemental compositions for structural elucidation. Compared to traditional workflows, impurity identification using UNIFI was >250× faster.

Conclusions
The combination of UPLC, SELECT SERIES MRT, and the integrated UNIFI elucidation toolset enabled a streamlined approach for impurity analysis in complex pharmaceutical samples.

References
1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (n.d.). ICHM7 Q&A and Its Support Document Available Now on ICH Website. ICH. Retrieved from https://www.ich.org/news/ich-m7-qa-and-its-support-document-available-now-ich-website.
2. Waters Corporation. (n.d.). UNIFI Scientific Information System. Waters Corporation. Retrieved from https://www.waters.com/waters/en_PR/UNIFI-Scientific-Information-System/nav.htm?locale=en_PR&cid=134801359.
3. Waters Corporation. (n.d.). Elucidation Tool: UNIFI Scientific Information System to Identify Unknown Compounds in Natural Products. Waters Corporation. Retrieved from https://www.waters.com/nextgen/pr/en/library/applicationnotes/2014/elucidation-tool-unifi-scientific-information-system-identify-unknown-compounds-natural-products.html

8) LC-MS/MS Analysis of N Nitrosopseudoephedrine in Pharmaceutical Products using Vitamin E as a Nitrite Scavenger

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Objectives
The recent discovery of carcinogenic N-nitrosamine impurities in pharmaceutical products are a significant health risk to patients. Many Active Pharmaceutical Ingredients (API) contain secondary or tertiary amine functional groups and are therefore at risk of being a source of N

nitrosamines when in the presence of a nitrite source. Nitrite scavenging compounds have the potential to reduce N nitrosamine formation during analysis and the associated risk of a false positive result. False positive results can have unnecessary financial implications for a pharmaceutical company by providing inaccurate results and reducing product availability to patients. This study describes experiments investigating N nitrosamine formation and inhibition via the use of Vitamin E as a nitrite scavenger for N-Nitrosopseudoephedrine in a major pharmaceutical company's drug product.

Method

N-Nitrosopseudoephedrine and deuterated N-Nitrosopseudoepedrine-d3 reference materials were obtained from Toronto Research Chemicals. ?-Tocopherol was obtained from Merck. Acetonitrile, methanol and formic acid were obtained from Fisher Scientific. Deionised Water was produced in-house. Drug product containing pseudoephedrine was supplied by customer.

Acetonitrile diluents were prepared containing a range of concentrations of vitamin E from 0 to 10 mg/mL. N-Nitrosopseudoephedrine calibration standards were prepared at a range of 0.4 – 30 ng/mL in diluent. 1 tablet was extracted in diluent using sonication and mixing steps. Sample solutions were spiked with sodium nitrite in a range of concentrations from 0 – 72 ng/mL.
Analysis was performed on an Acquity UPLC coupled to a Sciex 6500+.

Results

When in the presence of a nitrite source and favourable conditions, secondary and tertiary amines can form N nitrosamines. One such nitrite source is the presence of trace amounts of sodium nitrite in excipients used for drug manufacturer. Sub parts per million levels of sodium nitrite have the potential to form levels of N nitrosamine exceeding the regulators limit of 18 ng/day when present with an excess of API. A method developed to accurately determine N-nitrosamine levels in a drug product must consider if N nitrosamine formation is possible, and if so, take measures to prevent it occurring.
A major pharmaceutical company requested a method to quantify N-nitrosopseudoephedrine in an over-the-counter decongestant drug product. High levels of N-nitrosopseudoephedrine were observed so false positive results were performed.

An experiment was performed by adding a known amount of sodium nitrite to result in a specified N nitrosamine increase against an excess of pseudoephedrine API. Results showed an increase in N nitrosamine level for nitrite spiked solutions, indicating that N nitrosamine formation was possible during sample preparation using and that a false positive result was likely. A suitable nitrite scavenging compound was required to minimise N nitrosamine formation in solution while not negatively impacting the sample preparation and LC-MS-MS analysis.

A multitude of nitrite scavenging compounds exist with different chemical and physical characteristics to consider in relation to sample preparation steps. Vitamin E was selected due to its demonstrated nitrite scavenging ability and solubility in organic solvent required for sample dissolution. Experiments showed a significant reduction in N nitrosamine content when using vitamin E in solution, even with a nitrite source spiked in. Subsequent experiments optimised the extraction times and maximum concentration of vitamin E in solution possible, to improve method robustness to elevated amounts of nitrite present in the product.

The final method achieved an LOQ of 0.4 ng/mL in standard solutions with a linearity > 0.99 over a 0.4 – 30 ng/mL range. Samples spiked with N-nitrosopseudoephedrine achieved recoveries between 70 – 130%.

Conclusions

A method to quantify N-nitrosopseudoephedrine in a pharmaceutical company's drug product was developed and validated using Vitamin E as a nitrite scavenger. The risk of a false positive result was identified as N nitrosamine formation was shown to be possible during sample preparation. The use of Vitamin E as a nitrite scavenger provided quantification of the N-nitrosamine with reduced risk of false positive results while maintaining a highly sensitive, accurate and robust analytical method.

Speaker biographical details

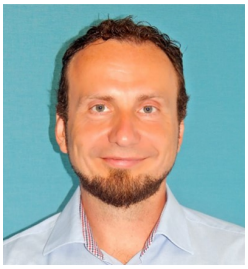
Sandra Furlanetto - University of Firenze, Italy
Sandra Furlanetto holds a PhD in Pharmaceutical Chemistry, she is Full Professor of Analytical chemistry at the University of Florence, she serves as Editor of Journal of Pharmaceutical and Biomedical Analysis from 2018; she is member of Italian National University Council. She was Rector's Delegate of University of Florence for student guidance from 2011 to 2021. She has highly contribute to the dissemination at both national and international level of the role played by multivariate strategies in analytical chemistry and pharmaceutical technology. She is expert in the application of QbD and AQbD to ensure the quality of analytical processes and pharmaceutical products.

Dr Richard Ladd - RML Consulting
Richard Ladd is a senior leader and consultant specialising in pharmaceutical development and manufacturing. With over 35 years of industry experience, he has worked across all stages of drug discovery, development, scale-up, manufacturing, and commercialisation.
Richard has a proven track record in scientific, project, and line leadership within Pharmaceutical R&D, regulatory CMC, and the analytical instrument industry. He is a passionate advocate for new technology adoption and a highly effective technical problem solver.
He is a regular speaker at international conferences, focusing on quality by design strategies, technology adoption for troubleshooting, and accelerating development timelines through novel technological solutions.

Stephanie Toulot - Novartis
Stephanie Toulot, PhD
Analytical Project Leader, Novartis Pharma AG
Stephanie is an analytical project leader at Novartis with deep expertise in defining analytical strategies for early phase development, advancing digital and innovative analytical lifecycle management approaches to enable efficient development and delivery of high quality medicines for patients worldwide.

Lewis Shipp, MBA
Director, Key Accounts, QbDVision
Lewis is a published pharmaceutical scientist who partners with multinational pharma, biotech, and CDMOs to deploy innovative Digital CMC solutions across their networks to accelerate the delivery of life-changing therapies to patients.

Dr Jean-françois Dierick - GSK
Jean-Francois Dierick holds a PhD In Biology from the University of Namur (Be), in the field of proteomics of cellular ageing and a post-doc in proteomics from the University of Brussels (Be). Jean-Francois Dierick entered the pharmaceutical world working for SGS, where he was leading the Biology Department from the site of Bierges (Be). Heigtheen years ago, he joined GSK Vaccines where he has occupied several positions related to analytics of biological products both in the development and the commercial areas. Today, he is working for GSK, in the Analytical R&D department, as Strategic Analytical Lifecycle Lead, being in charge of Analytical Lifecycle strategies (Analytical Method Validation, Transfer, Materials, …).



Szabolcs Fekete - Waters AS

Szabolcs Fekete received his PhD in Analytical Chemistry from the Technical University of Budapest. He worked in analytical R&D in the pharmaceutical industry for 10 years, then joined the University of Geneva in Switzerland as a research associate. He joined Waters Corporation in 2021 and is now a consulting scientist. His current interests include separations of new chemical modalities, fundamentals of chromatography, column technology and new method development approaches. He has co-authored ~230 publications (including peer reviewed journal articles, book chapters, handbooks and application notes).

Andrea Gheduzzi - Waters

Andrea Gheduzzi is a principal LC market development manager for EMEA at Waters Corporation. He spent more than 30 years in the chromatography field. Across his career he had various roles, service engineer, chromatography lab manager position, and technical manager for chromatography columns.

He has mainly been dealing with pharma accounts, also supporting LC method development activities using DoE/QbD approaches. In his previous role as Pharma Business Development Manager at Waters he has further expanded his expertise in AQbD and related applications.

Since 2023 he became principal LC market development manager for EMEA and member of the AQbD working party at the EDQM.

Amanda Guiraldelli Mahr - RIC

Amanda Guiraldelli Mahr is a Senior Scientist at the RIC Group in Belgium, leading the development and lifecycle management of analytical procedures for biopharmaceuticals under ICH Q14 and AQbD frameworks. She serves as a CMC analytical lead and subject matter expert for monoclonal antibodies, peptides, oligonucleotides, and RNA, supporting analytical strategies for release testing, stability studies, and characterization across CMC development. Her expertise spans chromatography and LC-MS workflows for large and small molecules, including structural characterization, impurity profiling and degradation studies. Amanda spent over 12 years at the United States Pharmacopeia (USP) as Senior Scientist and Scientific Affairs Manager, leading cross-functional initiatives on AQbD-driven method development, validation, reference standard characterization, and impurity analysis by LC-MS and GC-MS in collaboration with regulators and industry partners. She also held visiting scientist positions at TU Berlin and Leiden University, focusing on LC-HRMS–based protein analysis and method development.

Amanda currently serves as a member of the USP Pharmaceutical Analysis Lifecycle and Data Science Expert Committee and Chair of the USP Analytical Procedure Lifecycle Joint Subcommittee, responsible for USP general chapters related to AQbD and procedure validation (<1220>, <1221>, and <1225>), and is also a Board Member of the ECA Analytical Quality Control Group, contributing to global analytical standards and regulatory harmonization. She holds a Ph.D. in Analytical Chemistry and a bachelor’s degree in Pharmacy Biochemistry from the University of São Paulo, specializing in MS-based metabolomics and chemometrics.

Christian Haas - Agilent Technologies
Christian Haas is an R&D Scientist at Agilent Technologies, leading innovation in liquid chromatography by integrating data science with chemical applications. He has extensive experience in automated analytical chemistry, having worked on technology transfer and process optimization at Bayer, and on autonomous synthesis platforms coupled with online LC at MIT. Christian holds a PhD in Chemistry from Philipps-Universität Marburg, where he specialized in automated flow chemistry and analytical instrumentation.

Wiebke Holkenjans - Bayer Aktiengesellschaft
2000-2005: Studies in Chemistry (Hamburg and Münster, Germany)
2005-2008: PhD in Analytical Chemistry (online-coupling of electrochemistry / HPLC / mass spectrometry, Münster, Germany)
2009-2010: Application Chemist for hrMS applications (Bruker Daltonics, Bremen, Germany)
2010-2022: Lab Head Analytical Development for various functions, including API, DP, Special Analytical Technologies (Bayer, Wuppertal, Germany)
Since 2022: Scientific Lead Analytical Development NCE
- Implementation of new methods, concepts, regulatory requirements and digital tools in analytical development
- Scientific advisory for project teams and for investments
- Mentoring and development of learning concepts, implementation of state-of-the art analytical knowhow
- Building internal and external analytical communities and networks
- Development of academic and industrial partnerships

Arturs Kalimulins - ChromSword
Arturs Kalimulins is a Sales Director at ChromSword, bringing nearly 20 years of experience with the company. Over this time, he has focused on implementing ChromSword solutions across a wide range of customers—from academic laboratories to leading global pharmaceutical companies—helping them identify optimal ways to make HPLC method development more efficient, systematic, and reliable.
He specialises in guiding organisations from traditional experience-based approaches toward data-driven, controlled method development strategies, aligned with modern regulatory expectations such as ICH Q14.
Prior to joining ChromSword, Arturs Kalimulins worked as a Country Sales Director at Oracle Baltics, where he was responsible for implementing large-scale government-level information systems. This experience shaped his strong background in enterprise solutions, digital transformation, and complex project implementation.

Ilaria Neri - University of Cork

Ilaria Neri is a Postdoctoral Researcher in Analytical Chemistry at University College Cork, working within a collaborative research initiative with Pfizer. She completed her Ph.D. in Pharmaceutical Sciences at University of Naples Federico II, where her research focused on biomimetic liquid chromatography for investigating biological permeability and the toxicity of environmental contaminants.

Her work lies at the intersection of separation science, analytical method development, and data-driven modelling. She has extensive expertise in chromatographic techniques (LC-MS, GC-MS, SFC).

Her current research explores predictive chromatographic modelling by integrating experimental data with machine learning approaches to improve method development efficiency.

Dr. Neri has authored over 15 peer-reviewed publications and has presented her research at numerous international conferences. She has also gained international research experience at Edinburgh Napier University, where she developed advanced biomimetic analytical platforms and expanded her skills in in silico modelling and cell-based assays.

Her broader research interests include drug–biostructure interactions, permeability profiling, environmental contaminant analysis, and the sustainable extraction of bioactive compounds from agricultural waste. Alongside her research, she is actively engaged in science communication and education, contributing to teaching, public engagement, and outreach initiatives.

Dr Mikael Nilsson - Cambrex Karlskoga

Mikael Nilsson is Manager of R&D Analytical Development at Cambrex Karlskoga, where he leads activities within method development and validation. He has more than 15 years of experience in analytical characterization of drug substances and products, supporting development from early research through later stages. His interests include modern analytical strategies with main focus area on Chromatography.

Matthew Notley - AstraZeneca

Matthew Notley is a Senior Scientist at AstraZeneca, specializing in separation science, with a focus on high-throughput experimentation analysis and the development of robust, transferable, early-phase API stability-indicating methods. Prior to joining AstraZeneca, he worked at Pfizer as a Senior Separation Scientist, where he supported late-phase method development, method transfer, and troubleshooting.

Nathanael Page - Resolian

Nathanael Page is an Associate Scientific Director at Resolian, specialising in chromatography and mass spectrometry for the quantitation and characterization of trace impurities in pharmaceuticals and medical devices. With BSc in Forensic Science and an MSc in Analytical Chemistry from Loughborough University, Nathanael has provided technical guidance for the quantitation and characterization of nitrosamines and other impurities in numerous pharmaceuticals and medical devices. Nathanael's other research interests revolve around enhancing the sustainability of impurity quantitation and characterization methods.

Gesa Schad - Shimadzu European Group
Dr. Schad is an analytical chemist with a PhD in Pharmaceutical Sciences (University of Strathclyde, 2010). She holds a Diploma in Chemical Engineering (Technical University NTA, Isny) and an MSc in Pharmaceutical Analysis (Strathclyde). After roles in HPLC method development at the IAEA in Vienna and R&D at Hichrom Ltd. in the UK, she joined Shimadzu Europa's analytical business unit in Duisburg, Germany and became HPLC Product Manager in 2015. In this role Dr. Schad contributes to chromatography education through workshops, training courses and a social media Blog. She is also co?author of the recently published "SFC for Dummies" book, sharing practical expertise in supercritical fluid chromatography. Her work focuses on product strategy, customer relations and cooperative partnerships, coordinating application work and product support to advance chromatographic solutions through collaboration with academia and industry.

Mijo Stanic - Chromicent GmbH
Mijo Stanic is the managing director and co-founder of Chromicent GmbH and possesses 20 years of professional experience in the pharmaceutical industry, in addition to 5 years in biotechnology R&D. 15 years ago, he began integrating the concept of QbD together with UHPLC & SFC into his work and has continued to further develop it ever since.

Nina Trost - Novartis Pharmaceuticals
Nina Trost is a Senior Expert in Science & Technology working in analytical development, with a focus on method validation strategies and performance-based analytical approaches. Her work focuses on advancing performance-based approaches to analytical procedures, with particular emphasis on aligning practical implementation with evolving regulatory expectations (ICH Q14/Q2(R2)/Q12).
Nina leads cross-functional initiatives aimed at optimizing early validation and driving data-driven decision-making in analytical development. Her recent work focuses on leveraging platform approaches and company data to define performance-based criteria and increase flexibility in analytical procedures.

Dr Ewoud Van Tricht - Kantisto
Dr. Ewoud van Tricht has over 20 years of experience in the (bio)pharmaceutical industry. He has worked on small molecules, antibodies, proteins, viruses, and cell therapies at companies such as Abbott Healthcare Products, Janssen Vaccines, and Sanofi Cell Therapy. Alongside his full-time career, he completed a Bachelor's, Master's, and PhD in Analytical Chemistry. Ewoud specialises in Analytical Quality by Design (AQbD), having developed and implemented strategies to enhance pharmaceutical methods. He is passionate about optimising processes, coaching teams, and driving innovation through AQbD, Agile, and Lean methodologies, always striving for efficient and impactful results.

Maire Welham - AstraZeneca
An experienced analytical chemist with over 25 years in the pharmaceutical industry. Máire has worked on multiple small molecule projects as the analytical lead for both drug substance and drug product, spanning all phases from early development to marketing applications. Following a move into the Oligonucleotide space, Máire is enjoying the challenges of developing robust control strategies for these interesting class of molecules.

Delegate information

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