



Contribution To Standards Development For Next Generation Products

Eduardo BEREÁ
Alternative Ingredients

ENDS 2018 – London – 4-5 June 2018



2010s

- ❖ **Disposables / Cigalikes**
- ❖ **Rechargeable Cigalike & Cartomizers**
- ❖ **Fixed Voltage Devices**
- ❖ **Drip Tips**
- ❖ **Open System Atomizer – Single Top coil**
- ❖ **Variable Voltage Devices**
- ❖ **Replaceable Lithium Ion Batteries**
- ❖ **Internal Lithium Polymer Batteries**
- ❖ **Dual Bottom Coil Atomizer**
- ❖ **Variable Wattage Devices**
- ❖ **Adjustable Airflow**
- ❖ **Rebuildable Atomizers Tanks**
- ❖ **Mechanical Mods**
- ❖ **Sub Ohm Builds**
- ❖ **Higher Wattage Devices**
- ❖ **Stock Sub Ω Coils**
- ❖ **Resistance Based Temperature Control**
- ❖ **Replaceable Lithium Polymer Batteries**
- ❖ **Reactive Temperature Control**
- ❖ **...**



2010s

WHAT
NEXT
... ?



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OPEN

Health im
a prospec
regular d
smoked

Medical experts offered to debate
Canada's anti-vaping groups — but
they all refused

16 June 2017
3 October 2017

Asian vapers continue to suffer, and US study
spreads fresh misinformation

MEDICINE

E-cigarette flavors found to be toxic

Cancer Research blasts new vaping study

E-cigarette vapour enhances pneumococcal
adherence to airway epithelial cells

Pulmonology > Smoking & Tobacco

Long-Term E-Cigarette Use Could Increase Pneumonia Risk

— In vitro, in vivo studies show increased pneumococcal airway adhesion



Headlines

Once again [redacted] is behind specious pseudo-research. These results are pure propaganda, but meanwhile the media promotes this garbage to sell ads and profits. The

e-cigarettes are not so safe !

E-vapour leads to smoking

Study shows no effect

Heat-Not-Burn Tobacco Cigarettes

Smoke by Any Other Name

High-tech tobacco product illegal

ENDS = 95 TO JUUL or not to JUUL?

Students and faculty examine health implications of JUULing

Scientists find significant amounts of metals in e-cigarette vapors



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The Purpose of CORESTA

Encourage international cooperation
to actively work
on tobacco-related areas of research





Centre de
COopération pour les **RE**cherches **S**cientifiques
Relatives au **TA**bac

Cooperation Centre for **Scientific** Research Relative to Tobacco



The Vision of CORESTA

**To be recognised by our members
and relevant external bodies
as an authoritative source
of publically available credible
science and best practices
related to tobacco and its derived products**



What is CORESTA?

❖ It is a Non-profit Association:

- Founded in 1956 by 24 organisations from 20 countries
- Now 150 Member organisations from 38 countries
- Headquartered in Paris and governed under French law

❖ Main bodies

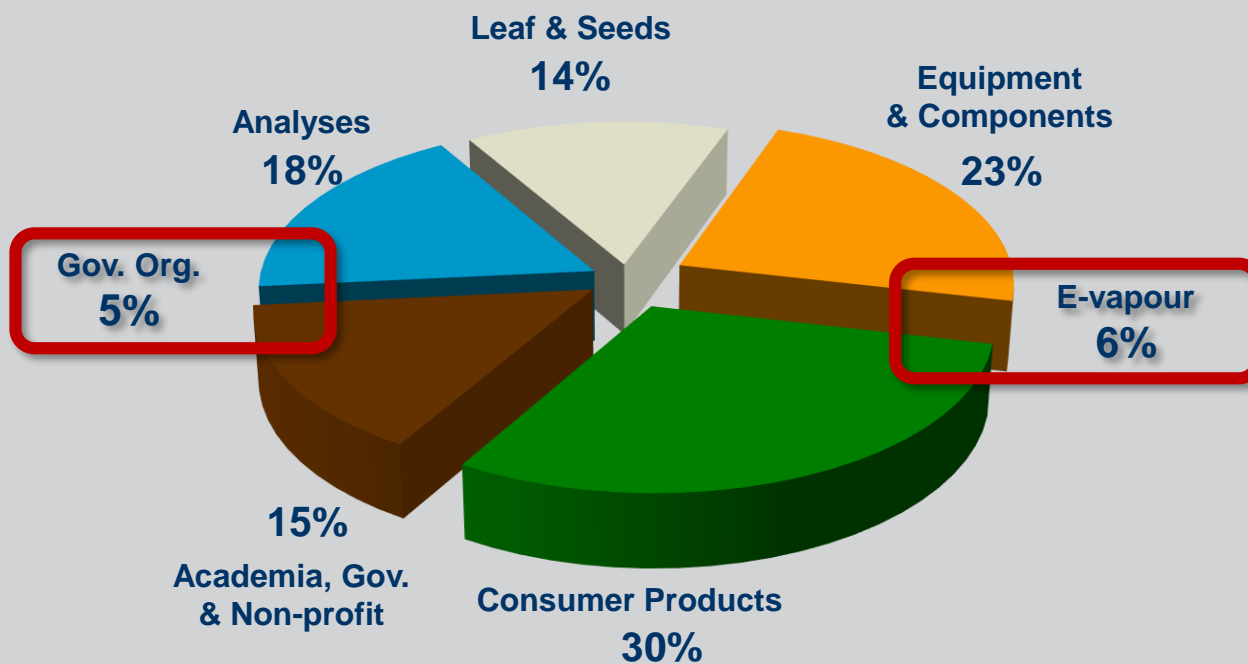
- Plenary member meeting (every two years)
- Board (12 to 14 elected member organisations)
- Scientific Commission (20 elected individuals)
- General Secretariat (3 persons)
- 23 Sub-Groups and Task Forces within 4 Study Groups + 3 inter-group committees

≈ 600 persons
worldwide involved
in on-going work

Currently 102 projects
leading to some 135 documents

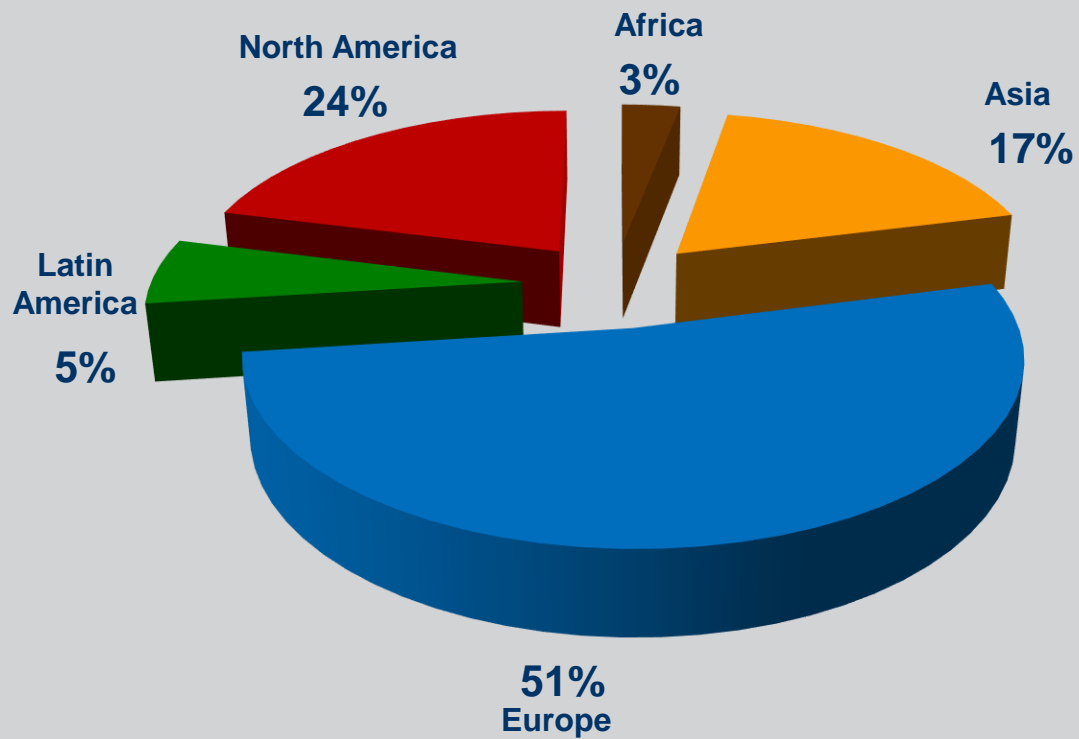


CORESTA Membership





CORESTA Membership





CORESTA Study Groups

❖ Agronomy & Leaf Integrity, Phytopathology & Genetics (AP)

- Agronomy & Breeding
- Curing
- Sustainability
- Pests & plant diseases
- Agrochemical issues

❖ Smoke Science, Product Technology (SSPT)

- Technical specifications
- Methods for component and emissions analysis
- Consumer behaviour
- *In Vitro* Toxicology



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❖ **Smoke Science**

- **SG Smoke Analytes**
- **SG Product Use and Behaviour**
- **SG Biomarkers**
- **SG In Vitro Toxicity Testing**

❖ **Product Technology**

- **SG Tobacco and Tobacco Product Analytes**
- **SG Physical Test Methods**
- **TF Cigarette Variability**
- **SG Routine Analytical Chemistry**
- **SG Cigar Smoking Methods**
- **SG E-Vapour**

- **Tobacco Heated Products (tbd)**



❖ **Smoke Science & Product Technology**

- **Developed Recommended Methods*, Guides and Reports on tobacco, product and smoke analysis (chemical and physical)**
 - 37 ISO standards based on CORESTA Recommended Methods (CRMs)
 - 6 CRMs currently in the process of becoming ISO standards (+2 updates)
 - Regular collaborative studies/proficiency trials to support member labs' accreditation (agrochemicals, TNCO, physical...)
 - Protocols for in vitro toxicity testing of mainstream smoke

**65 out of 86 CRMs are currently active, due to obsolescence/replacement of older ones*



SSPT Achievements

❖ Smoke Science & Product Technology

➤ Developed Reference Materials

- Monitor test pieces (CM#)
for smoking machine set-up + 1 for LIP testing
- 4 smokeless tobacco products



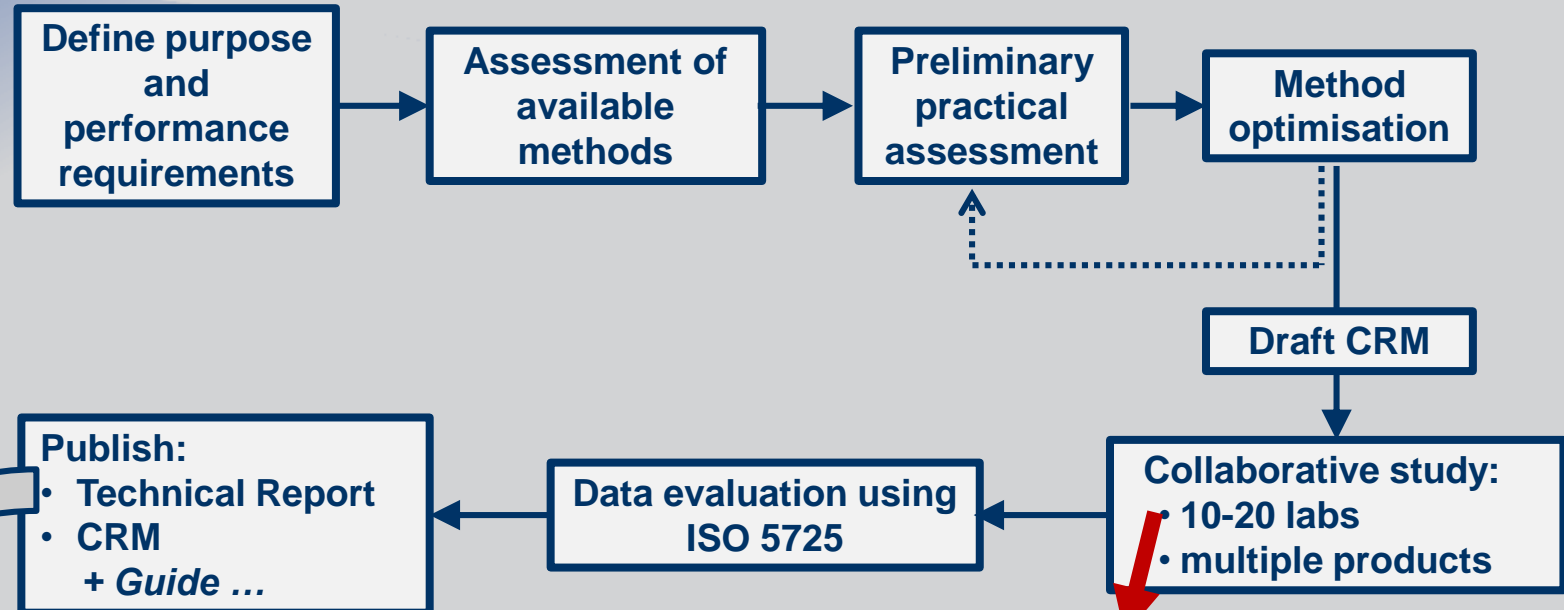


Development of Analytical Methods

Consensus-based process



Approach used for development of robust methods



www.CORESTA.org website
peer-reviewed publications

Need > 8, In-house, independent, government, academia ...

Discussions during the entire process provide insight into causes/reduction of intra- and inter-laboratory variability



Example:

CORESTA and e-cig standards



E-Vapour Sub-Group

- ❖ **Formed in 2013**
- ❖ **Currently 45 member organisations:**
 - **e-cig and e-liquid manufacturers,**
 - **equipment suppliers,**
 - **testing laboratories,**
 - **academia,**
 - **regulators**



Publications on CORESTA website

➤ 2014

- E-Cigarettes: A Brief Description of History, Operation and Regulation. Reference Report (February)
- E-Cigarettes: Assessment of Analytical Literature from 55 Studies Published Worldwide prior to November 2013 on Commercial E-Cigarettes. Reference Report (May)

➤ 2015

- E-Liquid Preliminary Proficiency Study. Technical Report (March)
- 2014 Electronic Cigarette Aerosol Parameters Study. Technical Report (March)
- CRM 81: Routine analytical machine for e-cigarette aerosol generation and collection - definitions and standard conditions (June)

➤ 2016

- Guide No. 18: Sample Handling and Sample Collection of E-Cigarettes and E-Vapour Generating Products (Nov.)

➤ 2017

- 2015 Collaborative Study for Determination of Glycerin, Propylene Glycol, Water and Nicotine in Collected Aerosol of E-Cigarettes. Technical Report (March)
- CRM 84: Determination of glycerin, propylene glycol, water, and nicotine in the aerosol of e-cigarettes by gas chromatographic analysis (March)

➤ 2018

- Guide N° 22 - Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices

➤ **Current development: Report and Method on Carbonyls and Metals in aerosol**



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- E-Liquid Preliminary Efficiency Study. Technical Report (March)
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➤ 2018

- Guide N° 22 - Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices

➤ **Current: CTR-CRM for Carbonyls in aerosol - Next: Metals in aerosol**

Basis for ISO/FDIS 20768
“Vapour products - Routine analytical vaping machine – Definitions and standard conditions”



Publications on CORESTA website

➤ 2014

- E-Cigarettes: A Brief Description of History, Operation and Regulation, Reference Report (February)

CRM84 → contribution in ISO 20714

“E-liquid — Determination of nicotine, propylene glycol and glycerol in liquids used in electronic nicotine delivery devices — Gas chromatographic method”

definitions and standard conditions (June)

➤ 2016

- Guide No. 18: Sample Handling and Sample Collection of E-Cigarettes and E-Vapour Generating Products (Nov.)

➤ 2017

- 2015 Collaborative Study for Determination of Glycerin, Propylene Glycol, Water and Nicotine in Collected Aerosol of E-Cigarettes. Technical Report (March)
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➤ 2018

- Guide N° 22 - Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices

➤ **Published May: Report Carbonyls in aerosol - Next: Metals in aerosol**



CORESTA **and International Standards**



Co-operation with standardization bodies

- ❖ **AFNOR (France)**
 - Member of the Tobacco & Tobacco Products Commission
 - CORESTA participated in the ECIG Commission
- ❖ **CEN (Europe)**
 - CORESTA Liaison with TC 437 Vape and Vapour Products
 - CORESTA-nominated experts in WG1, WG3 and WG4
- ❖ **ISO (International)**
 - CORESTA Liaison with TC 126 Tobacco and Tobacco Products and
 - SC1 Physical and Dimensional Tests
 - SC2 Leaf tobacco
 - SC3 Vape and Vapour Products
 - CORESTA leads SC3-WG2 on Vaping machine parameters



from CORESTA to ISO TC 126

- ❖ **CRM81 Vaping machine parameters**
 - **ISO 20768 – FDIS circulated June 2018**
- ❖ **CRM79 Ammonia in Tobacco**
 - **ISO 21045 – DIS approved February 2018**
- ❖ **CRM74 Carbonyls in Smoke**
 - **ISO 21160 – DIS approved January 2018**
- ❖ **CRM70 Volatiles in Smoke**
 - **ISO 21330 – DIS approved January 2018**
- ❖ **CRM72 TSNA in Tobacco**
 - **ISO 21766 – DIS approved January 2018**
- ❖ **CRM69 pH in Tobacco**
 - **New Work Item Proposal – submitted April 2018**
- ❖ **More to come on Carbonyls and Metals in e-liquids, Cigars ...**



from ISO TC 126 to CORESTA

❖ Revision of ISO 10362-1 Water in Smoke Condensates

- CORESTA Data requested by TC 126/WG 17
- CORESTA Report published March 2018

❖ TC 126 Resolutions

- *“That ISO/TC126/SC1 members agreed to revise ISO 2965:2009 accepting the CORESTA recommendations issued in CORESTA report [on air permeability]”*
- **Report submitted in view of becoming an Amendment to ISO 2965**
- *“That ISO/TC126/SC1 members agreed to revise ISO 9512:2002 following the CORESTA recommendations and the revised CRM 6 [ventilation]”*
- **Updated method submitted to ISO**
- *“That ISO/TC 126/SC 2 asks CORESTA to make available the results of its collaborative study [for Total alkaloids with safer chemistry]”*
- **CRM85 Total alkaloids with CFA using KSCN/DCIC → NP 22980**



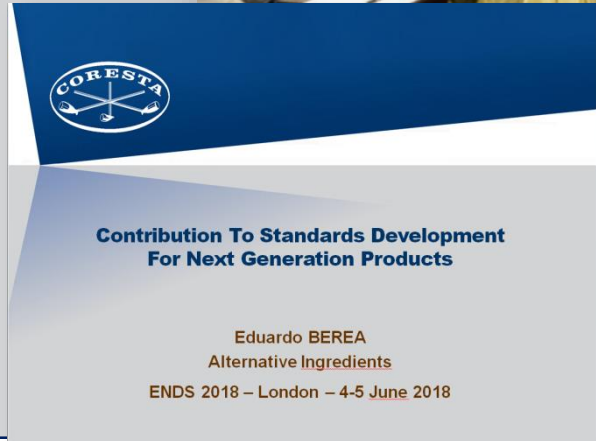
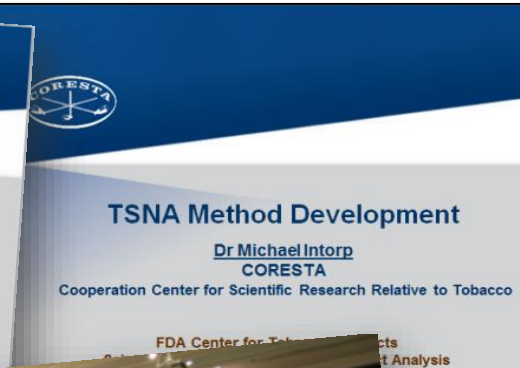
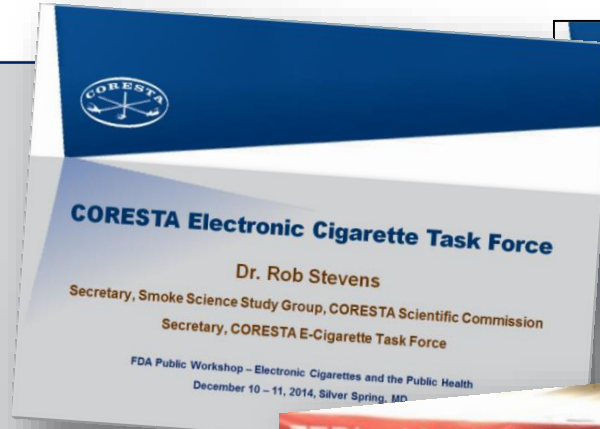
from ISO TC 92 to CORESTA

- ❖ **Alternative substrate for Low Ignition Propensity Testing**
 - **Feb. 2016:** Request that CORESTA perform the study
 - **March 2016:** Project launched within CORESTA
 - **April 2017:** Need for a specific test piece to be developed
 - **Dec. 2017:** 3 cigarettes tested → 1 selected
 - **May 2018:** Large study launched (17 laboratories & 3 substrates)



Stakeholder Engagement

- ❖ FDA Workshops
- ❖ Agrochemical Seminars
- ❖ Conferences
 - Global Tobacco & Nicotine Forum
 - Tobacco Campus
 - E-cig Europe
 - US Tobacco Merchants Association
 - Global Forum on Nicotine
 - Next Generation Nicotine
 - Filter Colloquium
 - ENDS 2017, 2018
 - ...





Value of collaboration: CORESTA

- ❖ **Over 60-year global interdisciplinary expertise from different sectors**
 - ❖ **Focus on sharing and advancing scientific knowledge**
 - ❖ **Large network to conduct inter-laboratory studies during development of analytical methods**
 - ❖ **Track record supporting development of International Standards**
 - ❖ **Emphasis on collaboration**
- non-members can get involved**



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Smoke by Any Name

High-tech tobacco
is illegal

ENDS = ... SOUL OF ... JUUL?

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Value of collaboration: CORESTA

**International
Multi-Stakeholder**

Robust

Science-Based Methods

Providing

Accurate

Reproducible

Comparable

Results



More information available
→ www.coresta.org



Cooperation Centre for Scientific Research Relative to Tobacco

Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac

Pierre-Marie GUITTON | Log out

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CORESTA Congress 2018

22-26 October 2018 -- Kunming, China

CALL FOR PAPERS [open](#)

Abstract submission deadline 16 May 2018

Science and Innovation: addressing the needs

Vision

To be recognised by our members and relevant external bodies as an authoritative source of publically available, credible science and best practices related to tobacco and its derived products.

→ [More about CORESTA](#)

News

CORESTA Presentation updated

09/04/2018

Project 185 launched: AA SG - Revision of CORESTA Guide No. 5 Technical No. #01 Maleic Hydrazide

06/04/2018

Project 184 launched: EVAP SG - Proficiency Study on the Determination of Metal Compounds in E-Liquids

06/04/2018

Project 178 launched: EVAP SG - Technical Guide for Designing E-Vapour Products and E-Liquids Stability Studies

26/03/2018

Project 183 launched: COR - Revision Guide No. 13 - Guidance for Sampling the Tobacco Leaf Supply Chain

Latest Documents

Reports

2015 Collaborative Study on Ammonia in Mainstream Cigarette Smoke

SMA Technical Report

23/03/2018

Recommended Methods

No. 82 - Determination of Benzo[a]pyrene in Tobacco Products by GC-MS

Fourth edition

19/03/2018

Recommended Methods

No. 79 - Determination of Ammonia in Tobacco and Tobacco Products by Ion Chromatographic Analysis

Second edition

19/03/2018

Reports

2017 Collaborative Study on Ammonia and Benzo[a]pyrene in Tobacco Products

Upcoming Meetings

10 April 2018

SG BMK - Biomarkers

Geneva, Switzerland

10 April 2018

SG PUB - Product Use Behaviour

Geneva, Switzerland

16 April 2018

SG SMA - Smoking Analytes

Guildford, UK

16 April 2018

SG RAC - Routine Analytical Chemistry

Guildford, UK

7 - 8 May 2018

Infestation Control Conference (ICC)

Winston-Salem, NC, USA