Best Practices Guidance for Advancing Research Initiatives and Combatting the Synthetic Drug Epidemic Workshop Series

Session I – July 17th from 1pm ET – 4:30pm ET
Session II – July 18th from 1pm ET – 4:30pm ET
Session III – July 25th from 12pm ET – 4pm ET

This online workshop series is focused on sharing information with the forensic analytical community to promote improved capabilities for NPS detection and measurement, as well as outreach to human and public health agencies and practitioners to promote better understanding of patterns of NPS use, diagnosis and treatment in the emergency room, and understanding of their role in determination of cause and manner of death, by collating and sharing information with emergency room physicians, medical toxicologists, and epidemiologists. The goal of this workshop series is to provide resource materials and promote a better understanding to the forensic science practitioner community of evidence based best practices regarding the synthetic drug epidemic.

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Session I – July 17th from 1pm ET – 4:30pm ET

1:00pm ET **30 min**	***A Working Model for Interdisciplinary Collaboration in Combatting the Synthetic Drug Crisis***	Barry K Logan, PhD, F-ABFT, Chief Scientist NMS Labs, Executive Director Center for Forensic Science Research and Education	There is increasing recognition that the interests of public health and public safety in the opioid crisis are very closely linked, and this is true across the whole spectrum of novel psychoactive substances. This presentation will consider the interests and capabilities of various stakeholders in early identification of novel substances using a model, now in place, linking drug interdiction at express-mail ports of entry, with rapid identification in seized drugs, retrospective datamining, toxicology method development, and dissemination through list-serves and online community groups. The presentation will focus on the importance of sharing the information with public health and public safety communities to assist with rapid method development and validation or scope updates, standards synthesis, collection and analysis of toxicological and death investigation data, which in turn can be distributed to the MDI community, public health officials and to policy makers to assist with early identification, scheduling decisions and strategies, research priorities, and resource allocation.
1:30pm ET **30 min**	***Identification of Novel Psychoactive Substances in Seized Drug Casework and the SWGDRUG Monographs***	Sandra Rodriguez-Cruz, Senior Forensic Chemist, DEA Southwest Laboratory, San Diego CA	Traditional color and microcrystal tests are not capable of identifying many of the new psychoactive substances (NPS) now part of the US illicit drugs market. This presentation will present an overview of the DEA's approach to the identification of NPS, including addressing key analytical challenges faced by drug chemists when analyzing NPS cases. The presentation will also discuss the role of the Scientific Working Group for the Analysis of Seized Drug Materials (SWGDRUG) in the development and posting of analytical information to assist with drug identification, including the collaboration with National Institute on Standards and Technology (NIST) on the verification of the analytical data.
2:00pm ET **30 min**	***Identification and Quantification of New Psychoactive Substances Without Authentic Reference Standards***	Ilkka Ojanpera, PhD, Department of Forensic Medicine, University of Helsinki, Pre-recorded	This pre-recorded presentation will highlight a novel approach for simultaneous identification and quantification of novel psychoactive substances (NPS) in blood without the necessity of authentic reference standards, using the combined approach of gas chromatography (GC) coupled to nitrogen chemiluminescence detection (NCD) and atmospheric pressure chemical ionization quadrupole time-of-flight mass spectrometry (APCI-QTOFMS). The presentation will also discuss the findings using the current analytical platform and applications not only in forensic and clinical toxicology, but also in other bioanalytical applications for the analysis of NPS.

2:30pm ET **45 min**	***Forensic Drug Testing in Urine by Nominal and High Resolution MS Analysis using Threshold Accurate Calibration***	Thomas Rosano, PhD, F-ABFT, Department of Pathology and Laboratory Medicine, Albany Medical Center, Albany, NY, USA. Clinical and Forensic Toxicology Laboratory, National Toxicology Center, Albany, NY, USA	Comprehensive drug screening has become more challenging in the evolving Opioids Crisis. Drug and metabolite (analytes) identification together with quantification is an important analytical tool in forensic and clinical toxicology. This presentation will focus on the development and validation of a definitive detection and quantification method (UPLC-MS-MS) for initial screening of 64 analytes in urine using a threshold accurate calibration (TAC) technique, which employs a rapid dual-specimen analysis i.e., with and without addition of a reference-analyte standard for normalization of matrix effects.
3:15pm ET **45 min**	***Screening Workflows for the Identification of NPS in forensic toxicology casework using High Resolution Quadrupole Time of Flight Mass Spectroscopy***	Alex Krotulski, MSFS, Research Scientist, Center for Forensic Science Research and Education	High-resolution mass spectrometry is being increasingly used in laboratories across the country as a first line drug screening strategy due to the high level of sensitivity, specificity, and rich data that is suitable for re-interrogation and retrospective datamining. This presentation will provide an in-depth review of the use of two powerful data acquisition modes as it pertains to laboratory screening for drugs of abuse by liquid chromatography time-of-flight mass spectrometry (LC-TOF). The capabilities and limitations of both data-dependent and data-independent acquisition modes, along with the specific laboratory applications of each mode will be discussed. The final component of the presentation will be demonstrating the effectiveness of this technique in solving complex drug screening problems.
4:00pm ET **30 min**	***Online Q&A and Discussion of Challenges in Method Development and Validation***	ALL PRESENTERS	

Session II – July 18th from 1pm ET – 4:30pm ET

1:00pm ET **45 min**	***Development of a Standard for Confirmatory Method Validation in Forensic Toxicology***	Melissa Kennedy, ANSI-ASQ National Accreditation Board	One of the most commonly cited documents related to method validation is based on the Scientific Working Group for Toxicology's (SWGTOX) method validation guidelines that were published in 2013. Since then, The Organization of Scientific Area Committees (OSAC) for Forensic Science has been formed to provide standardized approaches to analysis for the forensic toxicology community. The OSAC toxicology subcommittee has been tasked with developing these standards for implementation and incorporation into accreditation checklists. This presentation will focus on the integration of the SWGTOX validation document into an OSAC document and provide an update on its current status. The presentation will also discuss other regulatory documents being worked on by the OSAC Toxicology subcommittee and how those will impact current toxicology testing practices in the future.
1:45pm ET **45 min**	***Practical considerations in designing method validation studies for NPS assays***	Sherri Kacinko, PhD, F-ABFT, NMS Labs	One of the most challenging aspects of keeping current with emerging NPS is maintaining a relevant scope. Changes or modifications to the scope of testing require laboratories to perform either verification at a minimum, or more frequently complex validations, to show reproducible retention times and to assess sensitivity. Full method validation is often cumbersome, requires large amounts of instrument time and often pulls analysts from performing casework. This presentation will focus on practical considerations for designing method validation experiments for NPS that demonstrate method performance characteristics without requiring full method validation in an efficient timeline.
2:30pm ET **30 min**	***Qualitative Method Development and Validation for Synthetic Cannabinoids and experience with casework samples***	Marykathryn Moody, MSFS, NMS Labs	Synthetic cannabinoids have been increasing in prevalence in forensic casework since the late 2000's. The goal of this presentation is to provide a SWGTOX compliant approach to method validation for two classes of synthetic cannabinoids - the indazole carboxamides (NACA) and indoles, in whole blood. The performance characteristics of these methods will be discussed along with our experience with casework samples on different platforms. Additional topics covered in the presentation will include methods for keeping the scope of analysis relevant, resolution of isobaric compounds with similar structures, and the implications with respect to reporting drug positivity.

3:00pm ET **30 min**	***Quantitative Method Development and Validation for 18 Fentanyl Analogs and experience with casework samples***	Melissa Fogarty, MSFS, Laboratory Support Scientist, Center for Forensic Science Research and Education	Analytical challenges associated with the detection of fentanyl analogs has become a focus of many forensic toxicology laboratories. Many of the emerging analogs are isomeric in nature, which ultimately requires chromatographic resolution for identification. Comprehensive methods for the analysis of fentanyl analogs in the literature has been limited to a few compounds. This presentation will focus on the method development, including chromatographic separation for several isobaric fentanyl analogs isomers, and the subsequent validation using LC/MS-MS. The method includes resolution and identification of the following compounds: fentanyl, norfentanyl furanylfentanyl, butyrylfentanyl, methoxyacetylfentanyl, despropionylfentanyl, tetrahydrofuranylfentanyl, fluoro-isobutyrylfentanyl (FIBF), acrylfentanyl, para-fluorofentanyl, ortho-fluorofentanyl, carfentanil, α-methylfentanyl, β-methylfentanyl, isobutyrylfentanyl, para-methylfentanyl, cyclopentylfentanyl, cyclopropylfentanyl and β-hydroxyfentanyl. The final discussion will focus on the application of the method to whole blood specimens in postmortem toxicology cases.
3:30pm ET **30 min**	***Validation of an LC-MS-MS Method for the Analysis of Carfentanil, 3-Methylfentanyl, 2-Furanyl Fentanyl, Acetyl Fentanyl, Fentanyl and Norfentanyl Forensic casework.***	Eric Lavins, BS and Szabolcs Sofalvi MSChE, D-ABFT-FT, Cuyahoga County Regional Forensic Science Laboratory Cuyahoga County Medical Examiner's Office	In July of 2016, carfentanil (CF) emerged in Northeast Ohio resulting in over 25 deaths within a 30-day period. A total of 125 deaths have occurred in Summit County and Cuyahoga County has reported 40 deaths, relating to the presence of CF either alone, or in combinations with heroin and fentanyl. Prior to this surge in CF cases, positive fentanyl enzyme-linked immunosorbent assay (ELISA) screening results were increasing in number, but negative for fentanyl by GC/MS. The presentation will discuss a liquid chromatography tandem mass spectrometry method for the analysis of CF, acetyl fentanyl (AF), 2-furanyl fentanyl (2-Fu-F) and 3-methylfentanyl (3-MF) along with the quantitative values obtained in blood and vitreous humor in authentic antemortem and postmortem cases.
4:00pm ET **30 min**	***Online Q&A and Discussion of Challenges in Method Development and Validation***	ALL PRESENTERS	

Session III – July 25th from 12pm ET – 4pm ET

12:00pm ET **30 min**	***General Approaches to Toxicological Interpretation in Medicolegal Death Investigation with a focus on NPS cases***	Rob Middleberg, PhD, F-ABFT, D-ABCC-TC, NMS Labs	With the rapid emergence of NPS and the short duration on the market, the interpretation of NPS concentrations in medicolegal death investigations is difficult, due to a lack of reference literature. Oftentimes, case reports involving these emerging NPS fail to contain data that has been toxicologically confirmed or is limited by having a small sample size. When concentration data is available in the literature, the question becomes what the significance of this concentration is and how likely is that an NPS contributed toward the cause of death. This presentation will discuss the important of toxicology data in medicolegal death investigations and address issues with respect to interpretation as well as providing several cases as examples.
12:30pm ET **30 min**	***General Approaches to Toxicological Interpretation in Impaired Driving Investigations with a focus on NPS cases***	Barry Logan, PhD, F-ABFT, CFSRE, Aya-Chan Hosokawa, NMS Labs	The National Safety Council's Alcohol, Drugs and Impairment Division (NSC-ADID) recently provided recommendations for the toxicological investigation of suspected alcohol and drug-impaired driving cases and motor vehicle fatalities. In the most recent update in 2018, recommendations included adding fentanyl analogs, novel opioids and novel benzodiazepines to Tier II, which already includes several other NPS. Tier II compounds are not required as part of the recommended scope and should be included based on local prevalence. This presentation will address the NPS in Tier II, provide information related to effects associated with their use, concentration data and DUID case studies.
1:00pm ET **30 min**	***Outcomes based approaches to Toxicological interpretation and NPS in particular***	Simon Elliott, PhD, Alere Toxicology	Determining the toxicological significance of any drug case is often required, but this is especially true in cases where NPS are detected. However, poly-drug use with NPS makes this particularly difficult. This presentation will address this issue along with other factors to be considered prior to the interpretation of an NPS result. The presentation will describe an approach used to determine the significance of a particular drug using the toxicological significance score (TSS), which is widely used in Europe and allows for the qualitative assessment of drugs found in a case.
1:30pm ET **30 min**	***Medical Examiner Perspective on the use of Toxicological Data in NPS related cases.***	Amy Hawes, M.D., Knox County Medical Examiner	Autopsy findings are a critical component in medicolegal death investigations. The focus of this presentation will pertain to internal and external findings in suspected NPS overdose cases as well as new technology being incorporated into autopsies that may aid in the investigation of cases. Additionally, the presentation will highlight the importance of toxicology data in these cases, how it is used in determining the cause of death, and issues associated with the complexity of polydrug cases.

2:00pm ET **30 min**	***Summaries of Case Reports and Drug Concentrations of Major NPS categories: Cathinones and Benzodiazepines***	Donna Papsun, MS, D-ABFT, NMS Labs.	Synthetic stimulant drugs derived from cathinone and designer benzodiazepines have recently emerged on the NPS market and have been implicated in a number of impaired driving cases, fatalities and illnesses. Toxicity and death associated with the use of synthetic stimulants is attributed to their effects on the sympathomimetic system. Unlike the synthetic stimulants however, many of the designer benzodiazepines were synthesized by pharmaceutical companies as therapeutic drugs but were never approved. Benzodiazepines are frequently ingested to counteract withdrawal symptoms from stimulant and hallucinogenic drugs and anxiety disorder when prescriptions cannot be obtained. Designer benzodiazepines are of concern due to their high potency leading to sedation and amnesia.
2:30pm ET **30 min**	***Summaries of Case Reports and Drug Concentrations of Major NPS categories: Opioids***	Amanda LA Mohr, MSFS, Center for Forensic Science Research and Education	The opioid epidemic, which has recently proliferated to include fentanyl and its analogs, is a major public health concern, as many users are unknowingly ingesting these drugs under the misconception they are using heroin, without an understanding of their potential life-threatening toxicity. In 2017 and 2018, case reports of fentanyl analogs including furanyl fentanyl, carfentanil, butyrylfentanyl, para-isobutyryl fentanyl, methoxyacetylfentanyl, cyclopropylfentanyl, acrylfentanyl and the reemergence of 3-methylfentanyl have been implicated in postmortem, and driving under the influence (DUI) cases, demonstrating the high rate of turnover and overall prevalence. The focus of this presentation will be on current trend data and case reports from NMS Labs and the literature, along with concentration data for several of these emerging opioids and fentanyl analogs.
3:00pm ET **30 min**	***Summaries of Case Reports and Drug Concentrations of Major NPS categories: Synthetic Cannabinoids***	Matt McMullin, MS, F-ABFT, NMS Labs	The synthetic cannabinoid drug market has continued to evolve since their first appearance in 2008 to include a wide variety of structural classes. This presentation will review the core structures and substitutions of the different synthetic cannabinoid drug classes and discuss the adverse effects associated with these drugs. Additionally, the presentation will provide a review of the literature, current trend data, case reports with drug concentrations.
3:30pm ET **30 min**	***Online Q&A and Discussion of Challenges in Interpretation of NPS Drugs***	ALL PRESENTERS	