



3<sup>rd</sup> International Congress on

# Microbiology and Pharmaceutical Microbiology

&

Annual Summit on

# Sexual & Reproductive Health

October 02-03, 2017 Atlanta, USA

## Keynote Forum

Day 1



## *Syra S Madad*

*New York City Health + Hospitals, USA*

### **Emerging infections and biotreats**

Recent health events of communicable diseases around the world and the ease with which diseases can travel from one country to another, underscore the need for healthcare facilities and systems to be ready to address a variety of communicable disease emergencies. A robust communicable disease preparedness and response plan that is flexible and scalable can serve as a foundation to bolster overall control, prevention and response and allow institutions to adapt to changing situations that increase patient and staff safety. This presentation will discuss the core elements in a response plan needed to respond to any infectious hazard using an all-hazards approach rooted in the emergency management sphere.

### **Biography**

Syra S Madad is nationally recognized leader in public health and special pathogen preparedness and response. She currently serves as Director, system-wide ebola and special pathogens program at NYC Health + Hospitals, Assistant Professor in the Graduate Biotechnology Program at the University of Maryland, and Core Faculty of the National Ebola Training and Education Center (NETEC), in addition she is a Fellow in the Emerging Leaders in Biosecurity Initiative at the Johns Hopkins Center for Health.

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### **Notes:**



## *Hope Mueller*

*Horizon Pharma Inc, Ireland*

### **Quality oversight of CMO's microbiology investigation**

**Statement of the Problem:** CMO partnerships can be challenging both for the CMO and the product owner, especially when a significant OOS or other microbiology investigation arises. We will be discussing the CMO relationship and best practices that will ensure consistent, reliable, and quality supply throughout a difficult investigation. There are optimal organizational designs for CMO's and product owners that increase the likelihood of a successful partnership and outcome of the investigation. Clearly defined roles, responsibilities, and accountabilities are required. How to take increased action in the event the CMO's performance is suboptimal or represents a compliance risk? Establish short term and long-term corrective actions to ensure regulatory compliance throughout and in response to a critical event. Real world and first-hand examples to be discussed OOS events in products on stability, facility impacting sterility failure, aseptic processing validation failures, and critical system events experienced at the CMO. The discussion will instruct the participants how to effectively partner with CMO to ensure safe and quality product is provided to patients.

### **Biography**

Hope Mueller has over 18 years in Contract Manufacturing or Contract Manufacturing Oversight. She has designed organizations as a Contract Manufacturer and as a Product Owner. She has experience in the pharmaceutical microbiology laboratory and most of her career was within and managing analytical laboratories. She has lead large teams ensuring consistent and reliable supply of quality product. She has managed relationships with virtual and big pharma clients, and overseen multiple vendors. Hopes expertise lies in quality, operations, and continuous improvement. She has hosted, participated and executed hundreds regulatory and client audits. She has expertise in aseptic filling, BFS, oral configurations, topicals, inhalants, and biologics. She has proven success in launching efficient systems and improving operational performance at all levels. She is an exceptional leader proving her skills through the construction, training and mentorship of highly productive teams.

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### **Notes:**



## *Ian James Martins*

*Edith Cowan University, Australia*

### **Bacterial lipopolysaccharides (LPS) accelerates diabetes: Acute epilepsy and neurodegenerative disease**

Diabetes in the world has reached epidemic proportions with mitochondrial disease related to programmed cell death in various cells. The nuclear-mitochondrial interaction in diabetes is defective with concerns that increased plasma levels of bacterial lipopolysaccharides (LPS) are involved in mitochondrial disease and programmed cell death. Western diets with overnutrition promote LPS absorption with increased plasma LPS levels. Drug therapy in diabetes has become essential to prevent mitochondrial disease but LPS effects override the drug therapeutic effects with mitochondrial apoptosis. LPS inserts itself into cell membranes and is now considered a major repressor of the anti-aging gene *Sirtuin 1* (*Sirt 1*) and is a competitive inhibitor of *Sirt 1* actions involved in the regulation of cholesterol and glucose homeostasis. LPS neutralizes apolipoprotein E relevant to membrane amyloid beta aggregation in diabetes and neurodegenerative diseases. Diagnosis of diabetes, dyslipidemia and nonalcoholic fatty liver disease may now involve plasma LPS levels in global communities to avoid inadvertent errors by other clinical tests. Healthy diets that activate *Sirt 1* actions are essential reverse chronic diseases in diabetes with low calorie diets essential to reduce LPS effects. Poor hygiene, skin lesions, microbiological food contamination and elevated intestinal LPS transport induce LPS mediated mitochondrial apoptosis that supersede adenosine treatment relevant to recurrent epilepsy and seizures in diabetes and neurodegenerative diseases.

#### **Biography**

Ian James Martins has been invited to join the editors of various international journals and has been a reviewer for various journals (approx. 40). He was appointed as the Chief Editor for *International Journal of Diabetes Research* (2014-2017). He is a BIT Member (BIT Congress. Inc) with an H-index of 42, (ResearchGate STATs (22), Mendeley STATS (20). The total citations over the past 27 years has accumulated to 2830. ResearchGate's analysis available on google, Tweet, Facebook, LinkedIn. He has received certificates of recognition at various conferences/congresses in relation to anti-aging medicine. Prevention of over eating by food restriction improves the peripheral sink hepatic a beta clearance relevant to liver lipid metabolism important to improving health and global chronic diseases.

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## Keynote Forum Day 2



## *Marcela Rodríguez*

*Laboratorios SFC, Colombia*

### **Technics validation of microbiological quality control in pharmaceutical industries: Study of Colombian challenge**

**Statement of the Problem:** As happened in the entire world, Colombia's pharmaceutical industries had been one of the most regulated economic sectors, which has been good because of the development in the industries giving more dynamics and reaching important levels in quality control. One year ago, INVIMA, the government entity in charge of food and drug regulation, published a legal requirement in which all quality control laboratory has to implement GLPs, (good laboratory practices). With this requirement, laboratories began to define processes that assure the quality of their results. GLPs established necessity to study and formalize the microbiologist quality control, this is the opportunity to validate techniques and show the media the real role of microbiologist in the pharmaceutical industries.

**Findings:** The first step was to understand the principal techniques to validate, with the difference that we are talking about organisms; the approach was to physiochemical analysis and those not given all the answer to begin the validation process. We understood that is very important to validate techniques, that the microbiologist should know the pharmaceutical product since its manufacturing development and even the most important raw materials characteristics; it has been critic to eliminate possible interferences. Another important point (for me the most) is the inoculum standardization; in this process is very important to know the microorganism and its life cycle, if you do not know how it works, it is possible that you say it is an inhibition because you do not recover the exact quantity of inoculum.

**Conclusion:** The inoculum standardization is the base of techniques validation and giving key information to show the robustness, uncertainty and others important attributes, when you give a result in a microbiological test, like microbiologists, we have a challenge to show how all of this is critical in the pharmaceutical quality.

### **Biography**

Marcela Rodríguez is an Industrial Microbiologist, specialist in Quality Management. She has her expertise in Quality Control in pharmaceutical industries, specifically in microbiology lab. Early, she has investigated in Bioremediation of oily sludge, one of the most important environment problems in oil and gas industries in Colombia. Currently, she has worked like consultant of different pharmaceutical enterprises in Colombia, supporting the implementation of good laboratory practices and accreditation of microbiological analysis techniques as well as in the training of auditors of regulatory entities of the pharmaceutical sector in Colombia. She has worked for more than 15 years in the Colombian pharmaceutical industries.

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## *Rui Jin*

*Emory University, USA*

### **Antiviral compounds against ZIKV in sub-genomic reporter replicon**

As the Zika virus (ZIKV) continues to spread through the Americas and with hundreds of imported cases in the United States. Here, we describe a developed a Renilla luciferase reporter sub-genomic replicon of ZIKV, we also established stable cell lines harboring the replicon RNA. The cell lines will stably have expressed the non-structure part of viral RNA and proteins, which are noninfectious and can be used to quantify viral translation, RNA replication and anti-viral drug screen. We also test several clinical trial drug candidates for their EC50 both in Bhk21 and Huh7 cells and compared their differences, several potent inhibitors of ZIKV and can be used as reference inhibitor for future screen and discovery. Mutations on this replicon are also made and test for their effect on viral replication.

### **Biography**

Rui Jin has completed his Bachelor's Degree in Biotechnology from Wuhan University, Wuhan, China, and his PhD in Biochemistry and Molecular Biology at Wuhan Institute of Virology, Chinese Academy of Sciences. His Doctoral program was aimed at investigating the autophagic mechanisms of Japanese Encephalitis viral infection and the mechanisms of immune evasion. After graduation, he undertook his Postdoctoral training at the Houston Methodist Research Institute, where his research was focused on inflammation mechanisms of *Flavivirus* infection. In 2015, he has joined EIDD with the goal of developing new dengue and zika virus replicon system for antiviral drugs testing and characterization. He has screened thousands of compounds to evaluate their antiviral effect.

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### **Notes:**

## *Veena Kumari HB*

*Department of Neuromicrobiology, NIMHANS, India*

### **Confirmation and molecular characterization of hospital and community acquired methicillin resistant *Staphylococcus aureus***

**Purpose:** Methicillin Resistant *Staphylococcus aureus* (MRSA) has spread globally in both hospital and community settings posing a major threat to global health. Increasing prevalence of healthcare-associated MRSA (HAMRSA) infections is most often based on wide dissemination of particular epidemic clonal lineages of the *S. aureus* population. Use of different methods of DNA-based molecular typing will reveal human-adapted MRSA and have been widely applied for studying MRSA.

#### **Methods:**

- This is a prospective study for 2 yrs. with a total target sample size of 600.
- Clinical *S. aureus* isolates from inpatients/outpatients=200
- Corresponding nasal sampling from clinical MRSA positive patients =200
- Community nasal *S. aureus* isolates=200
- *S. aureus* isolates from clinical specimens like wound swabs, tracheal aspirates, bronchial lavage, cerebrospinal fluid, brain abscess pus, blood, shunt tips, central line tips etc submitted to Neuromicrobiology laboratory NIMHANS formed the study material
- Corresponding nasal sampling of the patients with MRSA isolates in the above clinical specimens was performed
- Isolation, identification and confirmation of the *S. aureus* as MRSA was performed by phenotypic laboratory methods as per CLSI guidelines

**Molecular characterization:** PCR I - 16srRNA (*Staphylococcus* genus specific), nuc (*S. aureus* species specific) and mecA (determinant of methicillin resistance) genes PCR II - SCCmec typing: SCCmec typing of the MRSA isolates to classify them as HA (Type I, II, III) and CA (Type IV, V) MRSA.

#### **Biography**

Veena Kumari HB has completed M.D Microbiology, and been serving as Additional Professor in the Department of Neuro microbiology, NIMHANS, with more than 15 years of experience in this discipline She has more than 20 papers in reputed journals and has been serving as Member Secretary, Hospital Infection Surveillance System of the Institute.

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