



CAPSIG NSW

(COSMETICS AND PHARMACEUTICAL SPECIAL INTEREST GROUP)

ABN 20 932 313 797

Endotoxin Testing – Doing the right thing?

Clinicians have formed the view that anyone with an infection of Gram-negative bacteria can develop a life threatening prognosis caused by Bacterial Endotoxin (pyrogen, LPS, LAL, TAL, etc). As a result, it is mandatory for manufacturers to perform endotoxin testing to ensure the safety of their product.

The traditional rabbit pyrogen test (animal testing) has all but disappeared. Newer rapid methods have been developed, however, choosing which method to use can be very confusing. As technology advances, methods such as recombinant Factor C Test (rFC), have been developed and made commercially available. This seminar will explore how robust these newer test methods are compared with USP compendial methods for endotoxin testing.

To ensure that there are no threats posed to the general population from endotoxin contaminated products, Regulatory bodies approve the use of various methodologies for testing for endotoxins in manufactured products prior to market release. Pharmaceutical, Radiopharmaceutical, Biotechnology and Medical Device Industries that manufacture cGMP product all require validated bacterial endotoxin release assays.

The Seminar will provide an insight into some of the challenges currently faced within these industries – from the perspective of validation and testing, and how the production and process control of a manufacturing facility can affect the endotoxin levels of their final products. It will be a useful guide to Quality Control Analysts, Manufacturing Quality Assurance Associates, Production Associates and Management.

Date: Wednesday 24th July 2019

Venue: Heritage Room, Canterbury Hurlstone Park RSL
20-26 Canterbury Rd, Hurlstone Park. NSW 2193

PROGRAMME

5:00 pm – 5.40 pm **Registration**

5:40 pm – 5:50 pm **Introduction: Yung Dai - CAPSIG Committee Member**

5:50 pm – 6.20 pm **Adam Smith - Immunobiology Section TGA Laboratories**
“Common Mistakes and Misconceptions with Endotoxin Testing”

6:20 pm – 6.50 pm **Tanya Spence and Renuk Bandaranayake- AstraZeneca (North Ryde)**
“Design of Pharmaceutical Water Systems for Exclusion of Endotoxins in Parenteral Products”

6:50 pm – 7:20 pm **Karolina Heed- Hyglos bioMérieux**
“Recombinant Horseshoe Crab Factor C (rFC): The Future is Here”

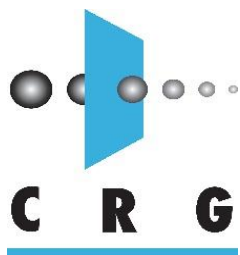
7:20 pm – 7:30 pm **Question Time followed by Dinner**

Cost: \$75.00 per person. **Cheques payable to CAPSIG - NSW.** (CAPSIG is a non-profit group with annual turn-over less than the statutory limit and hence GST is not applicable)

RSVP: Friday 19th July 2019

Bookings & Enquiries: Ms. Melissa J BOURKE
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Cheques and booking details to be sent to:
Ms. Melissa J BOURKE
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This seminar is proudly sponsored by:



BOOKING FORM

Names(s):	Company:	Address:	Email:	Phone:

TERMS AND CONDITIONS

1. Prior booking and payment in full are essential for seminar attendance
2. Payment must be made by the RSVP date of the seminar.
3. Payment must be in cheque or direct deposit (make sure you include your company/ name in the transaction).
4. All cheques must be made payable to CAPSIG NSW.
5. Direct deposit details listed below.
6. Cancellations must be made by the RSVP date, otherwise full cost of the seminar must be paid.
7. CAPSIG NSW is a non-profit group with an annual turn-over less than the statutory limit and hence GST is not applicable or charged. It is a Special Interest Group of the Australian Society for Microbiology Inc.
8. If you require an invoice please email Melissa at melissa.bourke@biomerieux.com

BANKING DETAILS

Account Name: CAPSIG NSW
Account No. 043238414
BSB: 112-879
Bank: St George