

2016 PDA INDIA CHAPTER MEDIA FILL WORKSHOP



29th November | Vivanta by Taj— Dwarka | Delhi

In the aseptic processing of medicinal products, the product quality usually cannot be ensured by means of lab controls of the final product. Process validation by means of media fills is one of the accepted norms to furnish proof of product safety, which is why it justly is the focus of regulatory requirements and official inspections. A number of revised and harmonised international regulations, especially the FDA Guidance for Industry, Sterile Drug, Products Produced by “Aseptic Processing”, the EU GMP Guide Annex 1, ISO 13408 and the PIC/S Guide “ Recommendation on the Validation of Aseptic Processes”, define highly detailed requirements, the implementation of which is critically examined within the framework of official inspections. In general, the required media fills should be able to simulate both routine operation and worst-case conditions.

For the first time PDA India Chapter brings a platform for discussion , to provide interpretation of guidelines and regulatory action for Media Fill with live case studies and examples.

Participants will have the unique opportunity to discuss -

- Principles of Media Fill
- Regulatory expectations and practical elements
- Designing Media fill studies
- Defining and executing interventions
- Evaluation of Media Fill Failures
- What to do when a run fails

Who will benefit


- Production
- Quality Assurance
- Microbiological Quality Control


who are responsible for the planning and evaluation of Media fill programmes. It is also valuable for decision makers who have to deal with media fill data within the framework of production release and Aseptic Process validation.



For further details please contact

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Don't miss the opportunity to hear from industry experts

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On 29th November at Delhi



REGISTRATION FORM

Registration Fees

Delegate Fee For Members from Indian Regulatory Body	Basic Rate	Service Tax 14%, .05% Swatch Bharat & .05% Krishi Kalyan As levied by Govt Of India	Total INR
PDA Member	2,635	395	3,030
Non Member	2,843	600	3,270

Participants Details

Dr. Mr. Ms.

Name

Designation

Department

Organization

Address of correspondence

City

State

Pin

Telephone Number

Mobile Number

Email Id

Payment Details

Cheque/DD NO.

Dated

Bank Drawn on

Terms & conditions

1. All registration will be considered complete only after the registration forms and payments are received.
2. Refund towards cancellation of participation will not be made, however participants can be substituted any time.
3. PDA India Chapter is not responsible for any damage occurring due to cancellation, alteration or substitution of the program, nevertheless, in case of cancellation of the program, by organizers, 20% of the fee will be forfeited.
4. The facilitators for the session and agenda are finalized but any untoward circumstance may necessitate alteration/modification or substitution of topic or facilitator.

Payment Details

A/C. NO.052301601000201
BANK: CORPORATION BANK
Type of Account: Current
Branch: R.P.C.Layout
SWIFT code: CORPINBB
RTGS/NEFT IFSC Code :
CORP0000523

Cheque / Demand Draft / pay order to be released on "PDA INDIA SOCIETY", Payable at Bangalore.

PDA INDIA SOCIETY is registered under 80G/12A, hence TDS deduction is not applicable

Payment Information

Completed form, along with draft/cheque made to PDA India Society should be sent on or before 14.11.2016 to:

PDA India Chapter

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