General Information - Registration

This workshop will look at aspects of "Extractables & Leachables" from many different angles: Definitions, Regulatory, Material & Polymer Science, Analytical E/L Methodologies, Safety Assessments and toxicology and assessment.

In addition, during the workshop, there would be multiple case study discussion and activities to improvise the learning.

Topics of discussion

- Polymers in the Sterile Drug Products-Sources & Effects
- Regulatory requirements-US FDA/MHRA/EU/WHO/ANVISA
- Approaches for designing studies of E&L
- The Threshold approach and its execution-E&L
- Analytical Techniques- The challenges in classical pharmaceutical molecules
- Leachables studies- Design & execution
- Selection of Closures-Points for consideration to avoid Rework
- Selection of Containers-Points for consideration to avoid Rework
- Formulation & Development Case Study for E&L
- E&L-Single Use systems
- Risk Assessment Techniques-Activity and the Case study
- Toxicology and assessment
- Extractables & Leachables in Pharmaceutical Packaging/Delivery System: USP Perspective

Who should attend

This course is for a team from

- R & D
- Quality Control
- Tech Transfer
- Regulatory Affairs
- Production

Venue

Novotel Hyderabad Airport
Airport Approach Road, Hyderbad, Telangana - 500409, India

Contact Information

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Agenda

Thursday, 4 July

9.00 a.m. - 9.30 a.m.
Introduction of PDA Inc. PDA India Chapter

9.30 a.m. - 10.20 a.m.
Polymers in the Sterile Drug Products-Sources & Effects

10.20 a.m. - 10.30 a.m.
TEA BREAK

10.30 a.m. - 11.20 a.m.
Regulatory requirements-US FDA/MHRA/EU/WHO/ANVISA

11.25 a.m. - 12.15 a.m.
Approaches for designing studies of Extractables & Leachables

12.20 p.m. - 1.10 p.m.
The Threshold approach -Extractables & Leachables

1.10 p.m. - 2.10 p.m.
LUNCH BREAK

2.15 p.m. - 3.00 p.m.
E&L-Single Use systems

3.05 p.m. - 3.55 p.m.
Analytical Techniques- The challenges in classical pharmaceutical molecules

4.00 p.m. - 4.15 p.m.
TEA BREAK

4.50 p.m. - 5.30 p.m.
Panel discussion, Q & A and Wrap up

Friday, 5 July

9.00 a.m. - 9.15 a.m.
Recap of Day 1

9.15 a.m. - 9.55 a.m.
Leachables studies- Design & execution

10.00 a.m. - 10.15 a.m.
TEA BREAK

10.20 a.m. - 11.00 a.m.
Selection of Closures-Points for consideration to avoid Rework

11.05 a.m. - 11.45 a.m.
Selection of Containers-Points for consideration to avoid Rework

11.45 a.m. - 12.25 p.m.
Formulation & Development Case Study for Extractables & Leachables

12.30 p.m.– 1.15 p.m.
Extractables & Leachables in Pharmaceutical Packaging/Delivery System: USP Perspective

1.20 p.m. - 2.00 p.m.
LUNCH BREAK

2.00 p.m. - 2.45 p.m.
Risk Assessment Techniques-Activity and the Case
Pharmaceutical formulation & Biotechnology Formulation

2.50 p.m. - 3.45 p.m.
Strategies & Tools for the Toxicology evaluation of Extractables & Leachables

3.45 p.m. - 4.00 p.m.
TEA BREAK

4.00p.m. - 4.50 p.m.
Panel Discussion

4.50 p.m. - 5.30 p.m.
Q & A, Felicitation and Wrap up