

# Visual Inspection Workshop Agenda

Thursday , 11th Of December 2014

Registration open 8.00 A.M - 9.00 A.M

Welcome and Opening Remarks 9.00 A.M. - 9.10 A.M.

## Session 1: Manual, Semi- or Fully Automated Inspection - Choices For Adoption 9.00 A.M. - 10.00 A.M.

This session will discuss the advantages and disadvantages of types of visual inspection systems available. Takeaway from this session will be to understand differences that exist between different type visual inspection method to aid in finalizing the best strategy of visual inspection for our individual industry

Presentation timing - 15 Minutes

Discussion - 45 Minutes

## Session 2: Regulatory expectations on Visual inspection and outcomes 10.00 A.M. - 11.00 A.M.

This session will discuss the regulatory expectations from various agencies, discussions on observations given to industry and their possible solutions

Take away from this session will be to have a clear cut understanding on regulatory expectations to aid in performing a gap assessment of current practices at our own sites.

Presentation - 15 Minutes

Discussion - 45 Minutes

## TEA BREAK

11.00 A.M. - 11.15 A.M.

## Session 3: Monitoring of Particulate Defects, Trending and identification for assessing risks 11.15 A.M. - 12.15 P.M.

This session will discuss the various options available for monitoring and Trending of particulate defects. Session will also discuss the advantages of use of the trending data on batch release.

Take away from this session will be to have a understanding on various methods available for trending, monitoring and identification of particulate defects.

Presentation - 15 Minutes

Discussion - 45 Minutes

## Session 4: Qualifying Visual Inspectors- The benchmarking process 12.20 P.M. - 1.20 P.M.

This session will discuss (a) methods and challenges in Qualifying visual inspectors (b) Understanding the Variables when Creating and Using Challenge Sets to Qualify Visual Inspectors

Take away from this session will be to understand a robust method of Qualifying a visual inspector & meeting quality expectations specifications

Presentation timing - 15 Minutes

Discussion - 45 Minutes

## JALDI '5'

13.20 P.M. - 13.30 P.M.

## LUNCH BREAK

13.30 P.M. - 14.00 P.M.

## Session 5: Setting up Limits for particulate rejects- Liquid Transparent , Liquid opaque , LYO , PFS 14.00 P.M. - 16.30 P.M.

During the breakout sessions participants with the help of Facilitator will discuss and develop plan / recommendations on Scientifically sound ways of setting up alert and action limit for visual inspection rejects.

Take away from this session will be to have a scientifically sound alert and action limits for each rejects which is one of the major Regulatory observations to the industry

(Attendees will be divided into 3 smaller groups to discuss this topic which will be led by a facilitator)

Expected outcome would be

- What is the expected rejects levels
- Setting up alert limits
- Setting up action limits
- Classifying Critical, Major and Minor rejects

## TEA BREAK

16.30 P.M. - 16.45 P.M.

## Session 6: Topic By Sponsors 16.45 P.M. - 17.30 P.M.

Group Discussion Summary 17.30 P.M. - 18.15 P.M.



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## Session 7: Qualifying automated Visual inspection machines - Case study

8.45 A.M. - 9.45 A.M.

This session will with an example of case study the process, acceptance criteria and statistical tools to qualify the visual inspection machines  
Takeaway from this session will be to understand the qualification methods for automated visual inspection machine used by Industry worldwide

Presentation - 15 Minutes

Discussion - 45 Minutes

## Session 8: Visual Inspection Rejects investigation

9.50 A.M. - 10.50 A.M.

This session will with an example of case study the process of investigation of visual inspection rejects and understanding the root cause. Takeaway from this session will be to understand the investigation methodology used worldwide for investigation of particulate rejects.

Presentation - 15 Minutes

Discussion - 45 Minutes

## TEA BREAK

10.50 A.M. - 11.05 A.M.

## Session 9: USP requirement of visual inspection and statistical sampling plans

11.05 A.M. - 11.50 A.M.

This session will discuss the new USP requirements on statistical sampling of visual inspection and specific requirements for Lyophilized products  
Take away from this session will be to have a clear understanding of the new USP requirement from an expert to understand the FDA expectations

Presentation - 15 Minutes

Discussion - 30 Minutes

## Session 10: X ray inspection - Advantages and Disadvantages (To be conducted by the sponsors)

11.55 A.M. - 12.30 P.M.

This session will discuss X ray inspection technology to understand the advantages and disadvantages

## LUNCH BREAK

12.30 P.M. - 13.15 P.M.

## Session 11: Challenges in visual inspection and solutions to ongoing bumps

13.20 P.M. - 15.30 P.M.

During the breakout sessions participants with the help of Facilitator will discuss various challenges during visual inspection and develop plan / recommendations on Scientifically sound ways of performing visual inspection of coloured solutions, powders, Lyophilized products etc  
Take away from this session will be to learning from each participants on the methods, technique used in inspection of difficult to inspect containers.

(Attendees will be divided into 3 smaller groups to discuss this topic which will be led by a facilitator)

Expected outcome would be

- Methods used for difficult to inspect containers
- Industry best practices on inspection of difficult to inspect containers

## TEA BREAK

15.30 P.M. - 15.45 P.M.

## Group Discussion Summary

15.45 P.M. - 16.30 P.M.

## Session 12: Topic By Sponsors

16.30 P.M. - 17.15 P.M.

## Gratitude & Closure

17.15 P.M. - 18.00 P.M.

