Table 17: Visual Inspection

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SCOPE:

Visual inspection involving particulate and defect assessment is an important element of the manufacturing and quality control of therapeutics. Visual inspection maybe accomplished manually or using a variety of automated inspection technologies. USP chapter <790> and monograph <1790> specify conditions and requirements for visual inspection while providing best practices when implementing and operating a visual inspection program. Further USP <1790> discusses a lifecycle approach, with an emphasis on continuous process improvement using project-specific inspection data collected through earlier phases.

This table will provide a forum for discussion of new developments in the field of visual inspection, practical aspects of manual and automated inspection methods, and regulatory and compendial requirements from participant experience with various product types.

QUESTIONS FOR DISCUSSION:

1. What are the key elements of a basic visual inspection program?
2. Acceptance Quality Limit (AQL) concept was introduced to overcome the burden of 100% visual inspection, how do you set practical acceptance criteria?
3. What constitutes a major vs. a critical defect? What are some approaches to updating and maintaining an appropriate defect list?
4. What are your experiences and learnings from holistic approaches to visual inspection process on control strategies such as AQL and defect trending?
5. How have you used inspection results and quality risk management concepts to drive continuous process improvements?
6. How do you apply the revised requirements of Annex 1 of the GMP guidelines for visual inspection?
7. How have you implemented the destructive testing approach for difficult-to-inspect products (i.e. reconstitution of lyophilized product, or dilution/filtration of opaque or colored products)?
8. Are there differences in visual inspection approaches for different product types such as cell and gene therapy and are the guidelines applied differently for different product types?
9. Are there differences in how health authorities and drug manufactures interpret “essentially free of particles” and acceptable AQL for liquid and lyophilized product?

DISCUSSION NOTES:

- USP <790> and <1791> are somewhat vague and need to be improved
- There is no standard for protein, how representative are the polystyrene beads?
- CMOs: Training is key, how is the defect library transferred and how are analysts trained against it?, bracketing for training -> train on a subset of defects
- New defects are not covered by library, how to integrate?
- Is re-inspection equivalent to reprocessing?
- Automated visual inspection leads to more rejected test articles, which will be re-inspected manually. Confirm AQL.
- Engineering run to verify lines (i.e. metal/metal, metal/glass contacts) for causing defects