

# Annual Product Review Developing an SOP

Presented by Steve Williams  
 Director – SeerPharma P/L  
 Sept 2010

## APR Objectives

Objective	FDA 211.180(e)	EUIPIC/s
Determine appropriateness, or need to change, product specifications	Required	Required
Same as above for starting materials	Not specified	Required
Need to change manufacturing procedures	Required	Not specified
Same as above for in-process controls	Required	Not specified
Verify consistency of existing process	Not specified	Required
Need for re-validation of processes	Not specified	Required
Highlight trends	Expected	Required
Identify product / process improvements	Not specified	Required
Identify corrective actions	Expected	Required
Consider previous reviews	Expected	Required
Grouping of products	Not allowed	Allowed

# Annual Product Review Sop

**ML Morrison**



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