

## **Table of Contents - Annual Reports: SOPs for Developing Content That Meets FDA Requirements**

Previous Presentations About SOPs .....	5
Dr. Sharlin's Credentials.....	6
Outline Of This Presentation.....	7
Benefits of Examining SOPs About Drugs, Biologics and Devices.....	8
Common Compliance Problems with SOPs .....	9
Purpose and Benefits of SOPs.....	10
Summary of SOP Development, Diagram.....	11
Summary of SOP Development, Diagram (2) .....	12
Summary of SOP Development, Diagram (3) .....	13
Required Activities For Each New SOP .....	14
FDA Guidances Contain Recommendations .....	15
Method Used To Write The Model SOPs.....	16
SOP Format: Section Headings.....	17
Features of the Model SOPs.....	18
How to Change Model SOPs .....	19
Factors That Affect Modification of Model SOPs.....	20
Electronic Submission of Annual Reports .....	21
eCTD Headings For Annual Reports .....	22

eCTD Headings For Annual Reports, IND References .....	23
eCTD Headings For Annual Reports, NDA References .....	24
Amount of Detail in an Annual Report.....	25
FDA Form 2252 For Annual Reports For NDAs, ANDAs and BLAs.....	26
FDA Form 2252 For Annual Reports For NDAs, ANDAs and BLAs (2).....	27
Annual Reporting of Postapproval Manufacturing, Package and Labeling Changes to NDAs and ANDAs.....	28
Model SOP #1, Biologics Annual Reporting.....	29
SOP #1, Biologics Annual reporting.....	30
SOP #1, Biologics Annual reporting.....	30
Model SOP #2, Device Annual Reports Required of Sponsors and Investigators Before Product Approval .....	40
SOP #2, Device Annual Reports Required of Sponsors and Investigators Before Product Approval.....	41
Model SOP #3, Device Annual Reports Required of A PMA Sponsor, Manufacturer or User Facility .....	52
SOP #3, Device Annual Reports Required of A PMA Sponsor, Manufacturer or User Facility.....	53
Model SOP #4, IND Annual Report .....	68
SOP #4, IND Annual Reports .....	69
Model SOP #5, Drug Post Approval Annual Reports .....	77
SOP #5, Drug Post Approval Annual Reports.....	78

How to Use The Model SOPs .....	92
How to Improve Your Annual Report Compliance .....	93
FDA Reviewer Likes and Dislikes Regarding Annual Reports .....	94
Summary of the Presentation: Annual Reporting SOPs .....	95
Next Steps .....	96
Joshua Sharlin, Ph.D., Resume .....	97