

## **Table of Contents**

# **Adverse Event Reporting SOPs for Drugs and Biologics**

<b>Previous Audioconferences About SOPs .....</b>	<b>4</b>
<b>Dr. Sharlin's Credentials .....</b>	<b>5</b>
<b>Outline Of This Presentation .....</b>	<b>6</b>
<b>Common Compliance Problems with SOPs.....</b>	<b>7</b>
<b>Purpose and Benefits of SOPs.....</b>	<b>8</b>
<b>Summary of SOP Development, Diagram .....</b>	<b>9</b>
<b>Summary of SOP Development, Diagram (2) .....</b>	<b>10</b>
<b>Summary of SOP Development, Diagram (3) .....</b>	<b>11</b>
<b>How Reviewers Examine Safety Data .....</b>	<b>12</b>
<b>How Reviewers Examine Safety Data (2).....</b>	<b>13</b>
<b>A Reviewer's Sources of Information for a Safety Review .....</b>	<b>14</b>
<b>How To Improve A Submission Using Information From the Reviewer Guidance on Evaluating Safety Data.....</b>	<b>15</b>
<b>How To Improve A Submission Using Information From the Reviewer Guidance on Evaluating Safety Data (2) .....</b>	<b>16</b>
<b>How FDA Uses MedWatch Data .....</b>	<b>17</b>
<b>April 2007 Guidance for Clinical Investigators, Sponsors and IRBs; AE Reporting – Improving Human Subject Protection (problem statement and participants).....</b>	<b>18</b>
<b>Flowchart of Current AE Reporting Relationships .....</b>	<b>19</b>
<b>Flowchart of FDA Recommended AE Reporting Relationships .....</b>	<b>20</b>
<b>April 2007 Guidance for Clinical Investigators, Sponsors and IRBs; AE Reporting – Improving Human Subject Protection (Conclusions).....</b>	<b>21</b>
<b>SOP Format: Section Headings.....</b>	<b>22</b>
<b>SOP Format: Details.....</b>	<b>23</b>
<b>How to Change Model SOPs .....</b>	<b>24</b>

<b>Required Activities For Each New SOP</b> .....	<b>25</b>
<b>Factors That Affect Modification of Model SOPs</b> .....	<b>26</b>
<b>Features of the Model SOPs</b> .....	<b>27</b>
<b>How To Use SOP Deliverables</b> .....	<b>28</b>
<b>Model SOP #1, IND Safety Reporting</b> .....	<b>29</b>
<b>Model SOP #2, IND Annual Reports</b> .....	<b>30</b>
<b>Model SOP #3, Postmarketing Safety Reporting for Drugs and Biologics: Responsibilities</b> .....	<b>31</b>
<b>Model SOP #4, Postmarketing Safety Reporting for Drugs and Biologics: Content</b> .....	<b>32</b>
<b>Model SOP #5, Validation of AE Data Capture Systems</b> .....	<b>33</b>
<b>Model SOP #6, Data Monitoring Committee</b> .....	<b>34</b>
<b>Model SOP #7, Statistical Analysis of AE Data</b> .....	<b>35</b>
<b>Model SOP #8, MedDRA Coding of AE Data</b> .....	<b>36</b>
<b>Summary of Audioconference; Adverse Event Reporting SOPs for Drugs and Biologics</b> .....	<b>37</b>
<b>Joshua Sharlin, Ph.D., Resume</b> .....	<b>38</b>