

### 15.D.10 Example of an SOP "Compilation and administration of operating procedures"

An example for an SOP for the "Compilation and Administration of SOPs" is provided on the following pages.

<b>Company name</b>		<b>Logo</b>	
<b>Operating procedure</b>		SOP no. QA-AD-001-01	
Title		valid from 1 January 2000	
<b>Compilation and administration of operating procedures</b>		Page x of y	
		Appendix 4 Replaces SOP no.	
Compulsory for Production Quality control Formulation Quality Assurance			
For information Central documentation			
Dr. Redneb	Quality assurance/ documentation officer	06.12.98	
created by	Job/role	Date	Signature
Dr. Rehtiep	Quality Assurance/ Head of Documenta- tion	07.12.98	
checked by	Job/role	Date	Signature
Dr. Saam	Quality Assurance/ Head of Department	08.12.98	
approved	Job/role	Date	Signature
Index of changes - new compilation			

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures"

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<b>Contents</b>	
1	Introduction
1.1	Background/objectives
1.2	Other relevant rules
1.3	Validity
1.4	Definitions
2	Implementation
2.1	Responsibilities
2.2	Layout, design and structure of an operating procedure
2.2.1	Cover sheet
2.2.2	Index of changes
2.2.3	Table of contents
2.2.4	Introductory section
2.2.5	Implementation section
2.2.6	Appendix
2.2.7	Distribution list
2.2.8	Receipt
2.3	Implementing an operating procedure
2.3.1	Compilation
2.3.2	Checking
2.3.3	Approval
2.3.4	Implementation
2.4	Training for operating procedures
2.5	Administration of operating procedures
2.5.1	Numbering and identification
2.5.2	Distribution
2.5.3	Archiving
2.6	Checking operating procedures
2.7	Changing an operating procedure
2.8	Withdrawing an operating procedure

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<b>1 Introduction</b>	
<b>1.1 Background/objectives</b>	
Important work processes must be set out in accordance with the rules of Good Manufacturing Practice. This must be done in writing. The processes must be described using operating procedures (process descriptions). This operating procedure describes rules for the compilation and administration of operating procedures in the company.	
<b>1.2 Other relevant rules</b>	
SOP Change Control	
<b>1.3 Validity</b>	
This operating procedure is valid for the compilation and administration of operating procedures in the areas of production, quality control, formulation and quality assurance in the company.	
<b>1.4 Definitions</b>	
Operating procedure (Standard Operating Procedure, SOP) To describe work processes to be implemented, safety precautions to be taken and other measures which are directly or indirectly relevant to the production of medicinal products.	
<b>2 Implementation</b>	
<b>2.1 Responsibilities</b>	
The responsibility for compiling an operating procedure lies with the manager of the department to which the operating procedure essentially relates. The manager can transfer the task of compiling the procedure to a qualified member of staff.	
<b>2.2 Layout, design and structure of an operating procedure</b>	
Operating procedures must be compiled using the relevant "SOP" format template. This sets out the formal requirements for the layout (e.g. headers/footers, font style and size, line spacing).	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<p>Operating procedures are composed of a minimum of the following sections:</p> <ul style="list-style-type: none"> <li>• Cover sheet</li> <li>• Change index</li> <li>• Contents</li> <li>• Introductory section</li> <li>• Implementation section</li> <li>• Appendices</li> <li>• Distribution list</li> <li>• Receipt</li> </ul> <p>These main sections can be extended if required.</p>	
<p><b>2.2.1 Cover sheet</b></p> <p>The cover sheet must contain at least the following information:</p> <ul style="list-style-type: none"> <li>• Company description / logo</li> <li>• Designation as an "Operating Procedure"</li> <li>• Title of operating procedure</li> <li>• Number of operating procedure</li> <li>• Date of validation:</li> <li>• Page number, number of pages</li> <li>• Number of appendices</li> <li>• Details of which operating procedure(s) are replaced by the existing SOP.</li> <li>• "Compulsory for"</li> <li>• "For information"</li> <li>• Signature of the compiler, the checker and the approver</li> </ul>	
<p><b>2.2.2 Index of changes</b></p> <p>The change index lists changes which have been made in relation to the previous edition as key points.</p>	
<p><b>2.2.3 Table of contents</b></p> <p>The table of contents is particularly useful for better orientation within a more extensive operating procedure.</p>	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<p><b>2.2.4 Introductory section</b></p> <p>The introductory section is structured according to the following points:</p> <ul style="list-style-type: none"> <li>• Background/objectives</li> <li>• Other relevant rules</li> <li>• Validity</li> <li>• Definitions/abbreviations:</li> </ul> <p>Background/objectives: the reason for the operating procedure is explained in the section entitled background/objectives, by specifying relevant regulatory requirements, for example.</p> <p>Other relevant rules: details of operating procedures with related content are given under this section. Such details should be provided with great care. On the one hand, understanding of the context is increased by specifying further literary sources; on the other hand, more maintenance is required in the event of modifications.</p> <p>Validity: the scope already defined on the cover sheet is further substantiated in the area of validity, e.g. by naming the manufacturing facility responsible for the content.</p> <p>Definitions/abbreviations: new terms are defined here and given abbreviations, if appropriate. These abbreviations can then be used in the text.</p>	
<p><b>2.2.5 Implementation section</b></p> <p>The processes to be regulated are described in the implementation section. The implementation section can be further structured depending on the contents of the operating procedure.</p>	
<p><b>2.2.6 Appendices</b></p> <p>The implementation section can be completed by <i>appendices</i>, e.g. checklists or forms which facilitate the processing of a procedure.</p> <p>Interchangeable appendices receive a version number with date. These appendices (e.g. forms, signature lists) can be updated if required, provided that they are still consistent with the contents of the operating procedure.</p> <p>The appendices are not included in the page numbering system for the operating procedure.</p>	
<p><b>2.2.7 Distribution list</b></p> <p>The distribution list itemises the sections to which the operating procedure must be distributed. The distribution list consists of the "compulsory" and "for information" recipients (see Appendix 1).</p>	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<b>2.2.8 Receipt</b> The <i>receipt</i> is used as documentary evidence that the recipient has received a copy (original copy) (see Appendix 2).	
<b>2.3 Implementing an operating procedure</b> The following steps must be worked through before an operating procedure is implemented. <ul style="list-style-type: none"> <li>• Compilation</li> <li>• Checking</li> <li>• Approval</li> </ul>	
<b>2.3.1 Compilation</b> New operating procedures should be compiled by a specially trained employee, i.e. an employee who is concerned in practice with the regulations of the operating procedures and is familiar with the workflows described therein. To co-ordinate a new operating procedure or a procedure to be reviewed, a draft must be compiled and distributed in a new commenting procedure for the purpose of attracting comments. Those participating in the commenting procedure are all the sections who will subsequently be affected by the contents of the operating procedure. The compilation is documented with the appropriate signature together with the name and role of the member of staff as well as the date that the operating procedure was signed.	
<b>2.3.2 Checking</b> After the text has been compiled, the operating procedure and its contents must be formally checked. The technical check must be conducted by a competent person who works independently of the compiler. Compliance with the design and format details will be formally checked by the quality assurance department. The analysis can be conducted by several persons depending on requirements (e.g. for operating procedures which need to be enforced for several sections). The check is documented with the appropriate signature together with the name and role of the checker as well as the date that the operating procedure was signed.	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<p><b>2.3.3 Approval</b>          Operating procedures must be approved by the person responsible before they are used.          The approval requires the suitability of the operating procedure to be checked and is granted by the person(s) who are responsible for the regulatory part of the document, e.g. quality assurance unit, head of production or head of quality control)          The approval is documented with the appropriate signature together with the name and role of the checker as well as the date that the operating procedure was signed.</p>	
<p><b>2.3.4 Implementation</b>          An operating procedure is considered to be <i>in force</i>, when all required signatures – compilation, checking, approval have been added and when the validation date has been reached.</p>	
<p><b>2.4 Operating procedure training</b>          To enable an operating procedure to be implemented, the employees concerned must know and understand the contents and be able to use them. To this end, <i>training</i> is provided on the operating procedure.          The responsibility for compiling an operating procedure lies with the manager of the department to which the operating procedure essentially relates. The department manager should plan and carry out the necessary training measures.          Newly compiled or revised operating procedures are explained as part of the initial training process. The scope of the initial training depends on the contents of the procedure and the group of recipients. The training measures can range from simply reading to practical demonstrations at the site of the event. Training on operating procedures must be documented.</p>	
<p><b>2.5 Administration of operating procedures</b>          The history of an operating procedure is accompanied by various administrative actions. These actions might include:</p> <ul style="list-style-type: none"> <li>• Compiling/maintaining overview lists in valid operating procedures</li> <li>• Numerical assignment</li> <li>• Monitoring the approval cycle</li> <li>• Identifying/distributing operating procedures</li> <li>• Monitoring the checking procedure</li> <li>• Archiving</li> </ul> <p>Depending on how an area is organised, operating procedures can be administered decentrally (e.g. throughout the company) or centrally (e.g. a documentation point/an employee appointed for SOPs).</p>	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>		
<b>Operating procedure</b>	SOP no. QA-AD-001-01		
Title	valid from 1 January 2000		
<b>Compilation and administration of operating procedures</b>	Page x of y		
<b>2.5.1 Numbering and identification</b>			
<b>2.5.1.1 Numbering</b>			
The operating procedures are numbered according to the following structure:			
AA -	BB -	111 -	22
AA: Compiling area			
BB: Subject area			
111: Serial number			
22: Version			
Each number may only be assigned once. The numbers are assigned by the administrative point.			
<b>2.5.1.2 Identification</b>			
The production of copies which are necessary for the further distribution of the operating procedure must be carried out under controlled conditions. The relevant version of the operating procedure is identified as followed in accordance with its status:			
<ul style="list-style-type: none"> <li>• Draft</li> <li>• Original</li> <li>• Original copy</li> <li>• Copy for information</li> </ul>			
The <i>original</i> is the copy of the operating procedure that bears the original signature from the approval process. The original is identified with the word "original" (in red) stamped on each page of the operating procedure. Pre-printed paper is used for this. If an original is replaced by a new version or is withdrawn, it must be identified as such by stamping the word "invalid" on the cover sheet.			
The <i>original copy</i> is a copy of the original. It is identified by printing the word "original copy" (in red ink) on each page of the operating procedure. Pre-printed paper is used for this.			
A <i>copy for information only</i> is not registered and is not subject to the change procedure. The recipient of this informative copy is responsible for keeping it up to date. It is identified by printing the "copy for information only" (in red ink) on each page of the operating procedure.			
A <i>draft</i> operating procedure does not show any compulsory work principles and is used to co-ordinate the contents of a new or revised operating procedure. It is identified by printing the word "draft" (in red ink) on each page of the operating procedure.			

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<p><b>2.5.2 Distribution</b></p> <p>The operating procedure is <i>distributed</i> to the area/persons listed in the operating procedure distribution list.</p> <p>Distribution must be carried out in good time before the validity date is reached and must be documented. The recipient confirms on the <i>receipt</i> that they have obtained a new or consecutive version or withdrawal or even destruction of the previous, now invalid version.</p>	
<p><b>2.5.3 Archiving</b></p> <p>The original version of the operating procedure and any replaced appendices as well as all checking forms are <i>archived</i> in the administrative section.</p> <p>The receipts are administered together with the distribution list. The history sheet (see Appendix 4) is then archived together with the operating procedure that was withdrawn.</p> <p>The <i>archiving time period</i> for operating procedures is 15 years.</p>	
<p><b>2.6 Checking operating procedures</b></p> <p>Operating procedures must be <i>checked</i> to ensure that they are up to date at regular intervals.</p> <p>Operating procedures must be changed immediately if the contents are changed. It will, however, be necessary to carry out a check after two years have passed.</p> <p>A checking procedure can have the following results:</p> <ul style="list-style-type: none"> <li>• "still up to date": The operating procedure will remain up to date for the next time interval.</li> <li>• "for review": The operating procedure will be reviewed; a consecutive version will be generated.</li> <li>• "for withdrawal" The operating procedure will be withdrawn.</li> </ul> <p>The results of checking an operating procedure are documented on an associated form, the distributees are informed of the result and the form is archived.</p> <p>It can be established when checking an operating procedure that it is necessary to change and update the contents and adapt them to the conditions which have been changed since the procedure was first compiled.</p>	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

<b>Company name</b>	<b>Logo</b>
<b>Operating procedure</b>	SOP no. QA-AD-001-01
Title	valid from 1 January 2000
<b>Compilation and administration of operating procedures</b>	Page x of y
<p><b>2.7 Changing operating procedures</b></p> <p>Changes in relation to the previous version will be listed as key points in the <i>index of changes</i>.</p> <p>Changing or updating an operating procedure will also entail a consecutive version with a new version number. The version numbering is a part of an operating procedure numbering system. In the event of more fundamental changes, it can also be necessary to compile a new operating procedure. The decision of whether or not a consecutive version or a new operating procedure should be compiled is taken by the compiler. Changes made throughout the history of an operating procedure are illustrated in an overview, the <i>history sheet</i> (see Appendix 4). The history sheet lists all changes between each version, including the appendices, in chronological order. The history sheet is not a part of an operating procedure but is centrally administered in the administrative unit.</p> <p>If changes are made, a consecutive version of the operating procedure is generated. When the consecutive version is implemented, the now invalid original of the previous version is marked as invalid and archived.</p> <p>If changes are made to operating procedures which have <i>contents which are relevant to the authorities</i>, (e.g. specifications of a manufacturing process or analytical procedure), the specifications of the change control program must be considered.</p>	
<p><b>2.8 Giving training on an operating procedure</b></p> <p>Operating procedures which have become invalid and which will not be replaced by a different operating procedure or consecutive version must be <i>withdrawn from circulation</i> in writing. This must be done using a form.</p> <p>Operating procedures withdrawn from circulation are destroyed by the sections/persons listed in the operating procedure distribution list. The destruction is documented and the department administering the operating procedures informed.</p>	
<b>End of operating procedure</b>	

Figure 15.D-4 Sample SOP "Compilation and administration of operating procedures" (cont.)

Company name	Logo		
Appendix 1 to SOP "Compilation and administration of operating procedures"	SOP no. QA-AD-001-01 valid from 1. January 2000		
<b>Distribution list</b>	Page x of y Replaces appendix no. ---		
<p>Compulsory for</p> <table border="0"> <tr> <td data-bbox="188 459 594 746"> <p><i>Production:</i>  Manufacturing company 1  Manufacturing company 2  Manufacturing company 3  Central weighing area  Documentation  Quality control  Laboratory 1  Laboratory 2  Laboratory 3  Documentation point</p> </td> <td data-bbox="611 459 941 746"> <p><i>Formulation:</i>  Development laboratory 1  Development laboratory 2  Development laboratory 3  Development laboratory 4  <i>Quality assurance:</i>  Documentation management  For information:  Central documentation</p> </td> </tr> </table>		<p><i>Production:</i>  Manufacturing company 1  Manufacturing company 2  Manufacturing company 3  Central weighing area  Documentation  Quality control  Laboratory 1  Laboratory 2  Laboratory 3  Documentation point</p>	<p><i>Formulation:</i>  Development laboratory 1  Development laboratory 2  Development laboratory 3  Development laboratory 4  <i>Quality assurance:</i>  Documentation management  For information:  Central documentation</p>
<p><i>Production:</i>  Manufacturing company 1  Manufacturing company 2  Manufacturing company 3  Central weighing area  Documentation  Quality control  Laboratory 1  Laboratory 2  Laboratory 3  Documentation point</p>	<p><i>Formulation:</i>  Development laboratory 1  Development laboratory 2  Development laboratory 3  Development laboratory 4  <i>Quality assurance:</i>  Documentation management  For information:  Central documentation</p>		

Figure 15.D-5 Appendix 1 to SOP "Compilation and administration of operating procedures"

<b>Company name</b>	<b>LOGO</b>
Appendix 2 to SOP "Compilation and administration of operating procedures"	SOP no. QA-AD-001-01 valid from 1. January 2000
<b>Receipt</b>	Page x of y Replaces appendix no. ---
<p>I hereby confirm receipt of the operating procedure &gt;Title of the operating procedure (number of the operating procedure)&lt;</p> <hr/> <p>date, signature</p>	

Figure 15.D-6 Appendix 2 to SOP "Compilation and administration of operating procedures"

<b>Company name</b>	<b>LOGO</b>
Appendix 3 to SOP "Compilation and administration of operating procedures"	SOP no. QA-AD-001-01 valid from 1. January 2000
<b>Checking the operating procedure</b>	Page x of y Replaces appendix no. ---
The operating procedure was checked with the following results:	
	"still up to date":
	"for review":
	"for withdrawal"
Reason for withdrawal	
<hr/> signature of the checker, date  <hr/> signature of the approver (for withdrawals only), date	

Figure 15.D-7 Appendix 3 to SOP "Compilation and administration of operating procedures"

