

# Contents

## File 1 to 3

<b>1</b>	<b>Quality Management</b>	
1.A	Quality management in the pharmaceutical environment	
1.A.1	Quality assurance in the GMP regulations	1.A (1)
1.A.2	From quality assurance to quality management	1.A (3)
1.A.3	Position of quality assurance in the company	1.A (4)
1.A.3.1	<i>Quality Unit as a staff function</i>	1.A (4)
1.A.3.2	<i>Quality Unit as a matrix function</i>	1.A (5)
1.A.4	Responsibility of the Quality Unit	1.A (7)
1.A.5	Tasks of a Quality Unit	1.A (9)
1.B	Documentation of a QM system	
1.B.1	Structure of a documentation system	1.B (1)
1.B.1.1	<i>Management board level</i>	1.B (3)
1.B.1.2	<i>Management/superiors</i>	1.B (4)
1.B.1.3	<i>Staff level</i>	1.B (4)
1.B.1.4	<i>Quality unit documents</i>	1.B (4)
1.B.1.5	<i>Procedure description and procedure instruction</i>	1.B (5)
1.B.1.6	<i>Operating procedure</i>	1.B (6)
1.B.2	Documents required in accordance with GMP	1.B (7)
1.B.3	Quality management handbook	1.B (9)
1.B.3.1	<i>Site master file</i>	1.B (9)
1.B.3.2	<i>Handbook in accordance with EN ISO 9001:2000</i>	1.B (11)
1.B.3.3	<i>Combined handbooks in accordance with GMP and ISO</i>	1.B (13)
1.B.3.4	<i>Functions of the quality management handbook</i>	1.B (17)
1.C	Quality management system in accordance with GMP	
1.C.1	Management responsibility	1.C (2)
1.C.1.1	<i>Responsibility of key personnel</i>	1.C (2)
1.C.1.2	<i>Responsibility of the management board</i>	1.C (2)
1.C.1.3	<i>Definition of quality policy</i>	1.C (5)
1.C.1.4	<i>Definition of quality objectives</i>	1.C (6)
1.C.1.5	<i>Support of the quality management system</i>	1.C (6)
1.C.1.6	<i>Deciding on resources</i>	1.C (7)

1.C.1.7	<i>Management review</i>	1.C (8)
<b>1.C.2</b>	<b>Change management system</b>	<b>1.C (9)</b>
1.C.2.1	<i>Definition of terms</i>	1.C (9)
1.C.2.2	<i>Processing of changes and deviations</i>	1.C (10)
1.C.2.3	<i>Processing of OOS results</i>	1.C (13)
1.C.2.4	<i>Involvement of external companies</i>	1.C (14)
<b>1.C.3</b>	<b>Complaints and recall</b>	<b>1.C (15)</b>
1.C.3.1	<i>Definition of terms</i>	1.C (15)
1.C.3.2	<i>Processing of complaints</i>	1.C (16)
1.C.3.3	<i>Responsibilities</i>	1.C (16)
1.C.3.4	<i>Compilation of a standard operating procedure (SOP)</i>	1.C (17)
1.C.3.5	<i>Recall</i>	1.C (21)
1.C.3.6	<i>Trend analysis</i>	1.C (22)
<b>1.C.4</b>	<b>Corrective and Preventive Actions (CAPA)</b>	<b>1.C (22)</b>
1.C.4.1	<i>Definitions</i>	1.C (23)
1.C.4.2	<i>Quality management system for CAPA</i>	1.C (23)
<b>1.C.5</b>	<b>Risk management</b>	<b>1.C (26)</b>
1.C.5.1	<i>Aims of risk management</i>	1.C (27)
<b>1.C.6</b>	<b>Qualification and validation</b>	<b>1.C (28)</b>
1.C.6.1	<i>Tasks of the Quality Unit</i>	1.C (29)
1.C.6.2	<i>Tasks of the management board</i>	1.C (29)
1.C.6.3	<i>Quality management system for qualification</i>	1.C (30)
1.C.6.4	<i>Quality management system for validation</i>	1.C (34)
<b>1.C.7</b>	<b>Training</b>	<b>1.C (35)</b>
1.C.7.1	<i>Compilation of a standard operating procedure (SOP)</i>	1.C (36)
1.C.7.2	<i>Compilation of an annual program</i>	1.C (36)
1.C.7.3	<i>Compilation of a training plan</i>	1.C (36)
1.C.7.4	<i>Guaranteeing participation</i>	1.C (37)
<b>1.C.8</b>	<b>Inspection</b>	<b>1.C (37)</b>
1.C.8.1	<i>Compilation of a standard operating procedure</i>	1.C (38)
1.C.8.2	<i>Contents of the audit program</i>	1.C (38)
1.C.8.3	<i>Contents of an audit plan</i>	1.C (39)
<b>1.C.9</b>	<b>Batch record review and annual product review</b>	<b>1.C (42)</b>
1.C.9.1	<i>Batch record review</i>	1.C (42)
1.C.9.2	<i>Annual product review</i>	1.C (44)
<b>1.C.10</b>	<b>Qualification of suppliers and service providers</b>	<b>1.C (45)</b>
1.C.10.1	<i>Responsibilities</i>	1.C (50)
1.C.10.2	<i>Risk analysis for grading</i>	1.C (50)
1.C.10.3	<i>Carrying out</i>	1.C (51)
1.C.10.4	<i>Requalification</i>	1.C (54)

## 2 Personnel

2.A	Place of work and job descriptions	
2.B	Requirements of the personnel	
2.B.1	Qualification requirements	2.B (1)
2.B.2	Health requirements	2.B (2)
2.C	Training	
2.C.1	Purpose of training	2.C (1)
2.C.2	Responsibility for training	2.C (1)
2.C.3	Requirements profiles/learning objectives	2.C (2)
2.C.4	Training contents and target groups	2.C (3)
2.C.5	Training planning	2.C (4)
2.C.6	Carrying out	2.C (4)
2.C.6.1	<i>External factors</i>	2.C (4)
2.C.6.2	<i>Qualification of the trainer</i>	2.C (5)
2.C.6.3	<i>Training methods</i>	2.C (5)
2.C.7	Reviewing the training and the training system	2.C (8)
2.C.8	Documentation	2.C (11)

## 3 Premises

3.A	Official requirements	
3.B	General requirements	
3.B.1	Location, connection to other rooms	3.B (1)
3.B.2	Size, area, height	3.B (2)
3.B.3	Installation and supply of utilities	3.B (3)
3.B.4	Lighting, ventilation, air-conditioning	3.B (4)
3.B.5	Hygienic construction	3.B (4)
3.B.6	Room book and layout	3.B (4)
3.C	Material flow, personnel flow and layout	
3.C.1	Material flow	3.C (1)
3.C.2	Personnel flow	3.C (2)
3.C.3	Layout	3.C (4)
3.D	Room classes	
3.E	Construction elements	
3.E.1	Walls	3.E (1)
3.E.2	Doors and windows	3.E (5)
3.E.3	Floors	3.E (7)
3.E.4	Ceilings	3.E (9)

3.F	Building services	
3.G	Room qualification	
3.H	Heating Ventilation Air Conditioning (HVAC)	
3.H.1	Introduction	3.H (1)
3.H.2	Room ventilation systems	3.H (2)
3.H.2.1	<i>Pure (100%) external air conditioning system</i>	3.H (3)
3.H.2.2	<i>Central recirculating air/mixed air conditioning system</i>	3.H (4)
3.H.2.3	<i>Decentralised recirculating air/mixed air conditioning system with central external air preparation</i>	3.H (5)
3.H.2.4	<i>Pure recirculating air conditioning system</i>	3.H (6)
3.H.2.5	<i>Systems for tempering and volume flow regulation</i>	3.H (6)
3.H.2.6	<i>Control-systems of the air volume flows</i>	3.H (8)
3.H.2.7	<i>Utilities for the operation of room ventilation systems</i>	3.H (8)
3.H.3	Filters	3.H (9)
3.H.3.1	<i>Particle air filter</i>	3.H (11)
3.H.3.2	<i>Suspended matter filter – HEPA-Filter</i>	3.H (14)
3.H.4	Principles for the design and planning of air conditioning ventilation systems	3.H (20)
3.H.5	Design criteria for the ventilation of premises	3.H (25)
3.H.5.1	<i>Air technology design of a sterile room with negative pressure plenum</i>	3.H (26)
3.H.5.2	<i>Pressure stages and design of the pressure differential measurement for a sterile area</i>	3.H (27)
3.H.6	Maintenance of air ventilation systems	3.H (33)
3.H.6.1	<i>Time intervals for carrying out inspections or servicing</i>	3.H (36)
3.H.6.2	<i>Tolerances for inspection and servicing deadlines</i>	3.H (36)
3.H.6.3	<i>Maintenance plan</i>	3.H (37)
3.H.6.4	<i>Forms for the inspection and servicing of ventilation systems</i>	3.H (37)
3.H.6.5	<i>Log book for air technology systems</i>	3.H (47)
3.H.7	Qualification of air conditioning ventilation systems	3.H (49)

## 4 Facilities and Equipment

4.A	Introduction	
4.B	Mechanical components	
4.B.1	Construction and installation materials	4.B (1)
4.B.2	GMP-compliant design characteristics	4.B (2)
4.B.3	Electrical and pneumatic components	4.B (3)

4.C	Control	
4.D	Facility concepts	
4.D.1	CIP (Cleaning in Place)	4.D (1)
4.D.2	Isolator technology	4.D (2)
4.D.3	Connected facilities	4.D (3)
4.E	Examples of facility qualification	
4.E.1	Design qualification	4.E (1)
4.E.2	Installation qualification	4.E (5)
4.E.3	Operational qualification	4.E (10)
4.F	Technical documentation	
4.F.1	Necessity	4.F (1)
4.F.2	Scope and content	4.F (2)
4.F.3	Administration of the technical documentation	4.F (8)
4.F.4	Log book	4.F (10)
4.G	Calibration	
4.G.1	Definitions	4.G (1)
4.G.2	Procedure	4.G (2)
4.G.3	Documentation	4.G (4)
4.G.4	Administration of scheduled calibration dates/times	4.G (4)
4.H	Maintenance	
4.H.1	Types of maintenance	4.H (1)
4.H.2	GMP-conform maintenance	4.H (2)
4.H.3	Systems for maintenance	4.H (3)
4.I	CIP (Cleaning in Place)	
4.I.1	Introduction	4.I (1)
4.I.1.1	Definition	4.I (1)
4.I.1.2	Cleaning mechanisms	4.I (2)
4.I.2	CIP systems	4.I (3)
4.I.2.1	CIP facility for stack cleaning	4.I (3)
4.I.2.2	CIP facility for lost cleaning	4.I (4)
4.I.3	GMP-conform design of CIP facilities	4.I (6)
4.I.3.1	Influences of the surfaces	4.I (6)
4.I.3.2	Requirements for pipes and tanks	4.I (6)
4.I.3.3	Requirements for bonding elements and seals	4.I (7)
4.I.3.4	Requirements for pumps	4.I (7)
4.I.3.5	Requirement for valves	4.I (9)
4.I.3.6	Requirements for measuring instruments	4.I (9)
4.I.4	Nozzle heads for container cleaning	4.I (10)
4.I.4.1	Spray ball	4.I (10)
4.I.4.2	Rotating nozzle head	4.I (11)

4.I.4.3	Targeted jet/orbital cleaner	4.I (11)
<b>4.I.5</b>	<b>Measuring technology</b>	<b>4.I (11)</b>
4.I.5.1	Flow measurement	4.I (12)
4.I.5.2	Pressure measurement	4.I (12)
4.I.5.3	Temperature measurement	4.I (13)
4.I.5.4	Conductivity measurement	4.I (13)
<b>4.I.6</b>	<b>Realisation of cleaning systems</b>	<b>4.I (13)</b>
<b>4.J</b>	<b>Containment (user protection)</b>	
<b>4.J.1</b>	<b>Significance</b>	<b>4.J (1)</b>
4.J.1.1	Use of isolators	4.J (2)
4.J.1.2	Working in the full protection suit	4.J (2)
<b>4.J.2</b>	<b>Definition of terms</b>	<b>4.J (2)</b>
<b>4.J.3</b>	<b>Containment grades of products in accordance with OEL</b>	<b>4.J (3)</b>
4.J.3.1	Measurement of the OEL values.	4.J (5)
<b>4.J.4</b>	<b>Containment weak points</b>	<b>4.J (6)</b>
<b>4.J.5</b>	<b>Containment systems for filling and emptying barrels and big bags</b>	<b>4.J (7)</b>
4.J.5.1	Barrel filling with endless liner	4.J (7)
4.J.5.2	Barrel filling and emptying with DCS (Drum Containment System)	4.J (9)
4.J.5.3	Big bag emptying and filling with a protective foil system	4.J (12)
<b>4.J.6</b>	<b>Container systems</b>	<b>4.J (13)</b>
4.J.6.1	Container with outlet cone for emptying	4.J (14)
4.J.6.2	Containment Transfer Unit (CTU) at the container inlet for filling	4.J (15)
4.J.6.3	Split valve systems	4.J (16)
4.J.6.4	Laminar flow, glove box systems (isolators)	4.J (17)
<b>4.J.7</b>	<b>Filter systems</b>	<b>4.J (18)</b>
<b>4.J.8</b>	<b>Sampling</b>	<b>4.J (19)</b>
<b>4.J.9</b>	<b>Containment on equipment</b>	<b>4.J (21)</b>
<b>4.J.10</b>	<b>Practical example of a containment API plant</b>	<b>4.J (23)</b>
<b>4.K</b>	<b>Process control systems</b>	
<b>4.K.1</b>	<b>Definitions</b>	<b>4.K (1)</b>
<b>4.K.2</b>	<b>Features of process control systems</b>	<b>4.K (2)</b>
<b>4.K.3</b>	<b>How to use process control systems</b>	<b>4.K (5)</b>
<b>4.K.4</b>	<b>Carrying out a process control system project</b>	<b>4.K (6)</b>
<b>4.K.5</b>	<b>Qualification of process control systems</b>	<b>4.K (7)</b>

## 5 Pharmaceutical Water

## 6 Qualification

<b>6.A</b>	<b>Official requirements</b>	
<b>6.A.1</b>	<b>Legal aspects of qualification</b>	<b>6.A (1)</b>

6.A.2	Documentation of the qualification	6.A (3)
6.A.3	Design Qualification (DQ)	6.A (4)
6.A.4	Installation Qualification (IQ)	6.A (7)
6.A.5	Operational Qualification (OQ)	6.A (8)
6.A.6	Performance Qualification (PQ)	6.A (9)
6.A.7	Qualification of established facilities	6.A (10)
6.A.8	Requalification	6.A (12)
6.B	Preparation of the qualification	
6.B.1	Commissioning	6.B (1)
6.B.2	Sequence	6.B (4)
6.B.3	Qualification team	6.B (5)
6.B.4	Responsibilities	6.B (6)
6.B.5	Qualification by external service providers	6.B (6)
6.B.5.1	<i>Integration of external capacities ("consultants") into the qualification process</i>	6.B (7)
6.B.5.2	<i>Transfer of parts of qualification activities to consulting engineers</i>	6.B (7)
6.B.5.3	<i>Transfer of qualification activities to suppliers, acquisition of qualification packages</i>	6.B (7)
6.B.6	Risk analysis	6.B (10)
6.B.6.1	<i>Risk analysis during the life cycle of a facility</i>	6.B (10)
6.B.6.2	<i>Organisation of risk analysis</i>	6.B (11)
6.B.6.3	<i>Implementation of the risk analysis</i>	6.B (12)
6.C	Qualification documentation	
6.C.1	Qualification master plan	6.C (2)
6.C.2	Qualification plan	6.C (3)
6.C.3	Qualification report	6.C (9)
6.C.4	Labelling of the qualification status	6.C (10)
6.C.5	SOP – "Qualification of facilities and equipment"	6.C (11)
6.D	Design qualification (DQ)	
6.D.1	User requirements (user specifications)	6.D (3)
6.D.1.1	<i>Example: Reaction vessel</i>	6.D (5)
6.D.1.2	<i>Example: Washer</i>	6.D (8)
6.D.2	Technical specification	6.D (12)
6.E	Installation qualification (IQ)	
6.E.1	Examples of IQ plans	6.E (3)
6.E.1.1	<i>Materials and lubricants</i>	6.E (4)
6.E.1.2	<i>Supply of (energy and media) utilities</i>	6.E (7)
6.E.1.3	<i>Measuring and control technology points and initial calibration</i>	6.E (9)
6.E.1.4	<i>Calibration records</i>	6.E (11)
6.E.1.5	<i>P &amp; I diagrams</i>	6.E (13)
6.E.1.6	<i>Pipes</i>	6.E (16)

6.E.1.7	Technical documentation	6.E (18)
6.E.1.8	<i>IQ report</i>	6.E (21)
6.E.2	<b>Example: Fluid bed equipment</b>	<b>6.E (23)</b>
6.F	<b>Operational qualification(OQ)</b>	
6.F.1	<b>Examples of OQ plans</b>	<b>6.F (3)</b>
6.F.1.1	<i>Safety devices</i>	6.F (4)
6.F.1.2	<i>Risk analysis Operating functions</i>	6.F (6)
6.F.1.3	<i>Check for the presence of screw caps</i>	6.F (8)
6.F.1.4	<i>OQ report</i>	6.F (11)
6.F.2	<b>Example: Fluid bed dryer</b>	<b>6.F (13)</b>
6.G	<b>Performance qualification (PQ)</b>	
6.H	<b>Special cases of qualification</b>	
6.H.1	Retrospective qualification	6.H (1)
6.H.2	Requalification	6.H (1)
6.H.3	Content of a review	6.H (3)
6.H.4	Maintenance of the qualified status	6.H (5)
6.H.5	Qualification of simple equipment	6.H (7)
<b>7</b>	<b>Process Validation</b>	
7.A	Official requirements	
7.A.1	Legal aspects	7.A (1)
7.A.2	The object of and procedure for process validation	7.A (2)
7.A.3	Process validation documentation	7.A (8)
7.B	Validation – a key element of quality assurance	
7.C	Process validation approaches	
7.C.1	Prospective validation	7.C (1)
7.C.2	Retrospective validation	7.C (2)
7.C.3	Concurrent validation	7.C (5)
7.D	Revalidation	
7.D.1	Time intervals for periodic revalidations	7.D (1)
7.D.2	Incidences requiring revalidation	7.D (2)
7.D.2.1	<i>Changes to the manufacturing instructions</i>	7.D (2)
7.D.2.2	<i>Extension of the ranges of critical process parameters</i>	7.D (4)
7.D.2.3	<i>Changes in manufacturing site</i>	7.D (5)
7.D.2.4	<i>Serious quality problems</i>	7.D (5)
7.E	Planning of process validation projects	
7.E.1	Responsibilities and task assignment	7.E (1)
7.E.2	Validation team	7.E (4)

7.E.3	Timing of validation	7.E (5)
7.E.4	Prerequisites for carrying out a validation project	7.E (6)
7.E.4.1	<i>What action should be taken if not all prerequisites have yet been fulfilled?</i>	7.E (10)
7.E.4.2	<i>Manufacture of a development or pilot batch in the run-up to a validation</i>	7.E (11)
7.F	Validation master plan	
7.F.1	Validation matrix	7.F (4)
7.F.2	Example of a validation master plan	7.F (6)
7.F.3	Example for a validation matrix	7.F (17)
7.F.4	Example for a test plan	7.F (24)
7.G	Risk analysis	
7.G.1	Finding out the adequate extent of validation	7.G (1)
7.G.2	Carrying out risk analysis	7.G (1)
7.H	Validation protocol and report	
7.H.1	Elements of the validation protocol	7.H (1)
7.H.2	Content of a validation report	7.H (9)
7.H.2.1	<i>How to deal with deviations from the requirements in the validation protocol</i>	7.H (10)
7.H.2.2	<i>Archiving of the validation documents</i>	7.H (11)
<b>8</b>	<b>Cleaning Validation</b>	
8.A	Official requirements	
8.B	Validatability of cleaning procedures	
8.B.1	Optimisation of cleaning procedures	8.B (1)
8.B.2	Compilation of cleaning instructions	8.B (5)
8.B.3	Validating manual and automated cleaning procedures	8.B (7)
8.C	Cleaning validation master plan	
8.D	Establishing the scope of validation	
8.D.1	Bracketing: determination of critical substances	8.D (1)
8.D.2	Matrixing: determination of equipment-specific validation protocols	8.D (5)
8.E	Acceptance criteria and limit calculation	
8.E.1	Calculation of active pharmaceutical ingredient residues	8.E (1)
8.E.2	Calculation of cleansing agent residues	8.E (9)
8.E.3	Determination of the microbial status	8.E (10)

8.F	Sampling procedures	
8.F.1	Swab test	8.F (1)
8.F.2	Rinse test	8.F (3)
8.F.3	Other procedures	8.F (6)
8.F.4	Selection of the appropriate procedure	8.F (7)
8.F.5	Microbiological testing of surfaces	8.F (8)
8.G	Analytical procedures	
8.G.1	Requirements for method validation	8.G (1)
8.G.2	Selection of the appropriate analytical method	8.G (6)
8.H	Documentation	
8.H.1	Validation protocol	8.H (1)
8.H.2	Validation report	8.H (3)
8.H.3	Other documents	8.H (7)
8.I	Maintenance of the validated status	
8.I.1	Changes and deviations	8.I (2)
8.I.2	Change control	8.I (2)
8.I.3	Revalidation	8.I (3)
8.I.3.1	<i>Change-related revalidation</i>	8.I (3)
8.I.3.2	<i>Periodic revalidation</i>	8.I (6)
8.I.4	New products and equipment	8.I (7)
8.I.4.1	<i>New products</i>	8.I (8)
8.I.4.2	<i>New equipment</i>	8.I (8)
8.I.5	Deviations	8.I (10)
8.J	Cleaning validation documentation (example)	

## 9 Computer Validation

## 10 Empty Register

## 11 Production

11.A	Sanitation	
11.B	Personnel hygiene	
11.B.1	Clothing	11.B (1)
11.B.2	Personnel hygiene	11.B (11)
11.B.3	Code of conduct	11.B (11)
11.B.4	Hand disinfection	11.B (12)
11.B.5	Health requirements	11.B (13)
11.B.6	Training	11.B (13)

11.C	Production hygiene	
11.C.1	Sources of contamination	11.C (3)
11.C.2	Cleaning	11.C (6)
11.C.3	Disinfection	11.C (7)
11.D	Sanitation programme	
11.D.1	Cleaning procedure for rooms	11.D (1)
11.D.2	Documentation	11.D (6)
11.E	Environmental monitoring	
11.E.1	Sampling plan	11.E (1)
11.E.2	Establishment of limits and frequencies	11.E (2)
11.E.2.1	<i>Methods</i>	11.E (4)
11.E.3	Investigation areas	11.E (6)
11.E.4	Evaluation	11.E (7)
11.F	GMP in the production process	
11.G	Weigh-in	
11.G.1	Legal principles	11.G (1)
11.G.2	Weigh-in principles	11.G (3)
11.G.3	Weigh-in procedure	11.G (4)
11.G.4	Weighing process sequence	11.G (6)
11.H	Identification	
11.H.1	Starting materials	11.H (2)
11.H.2	Labelling in the manufacturing process	11.H (3)
11.H.3	Labelling of rooms	11.H (6)
11.I	In-process control	
11.I.1	Objectives	11.I (1)
11.I.2	Organisation	11.I (3)
11.I.3	Carrying out	11.I (4)
11.I.4	Documentation	11.I (6)
11.I.5	Scope of tests and limits	11.I (7)
11.I.6	Responsibilities	11.I (7)
11.J	Prevention of cross-contamination	
11.J.1	Rooms and facilities	11.J (1)
11.J.2	Cleaning	11.J (2)
11.J.3	Labelling	11.J (3)
11.J.4	Personnel	11.J (3)
11.J.5	Reviewing the measures	11.J (4)
11.J.6	Manufacture of critical products	11.J (4)
11.K	Deviations	
11.K.1	Definition	11.K (1)

11.K.2	Sequence	11.K (2)
11.K.3	Responsibilities	11.K (4)
11.K.4	Measures	11.K (4)
11.K.5	Failure investigation report	11.K (5)
11.K.6	Evaluation	11.K (7)
11.K.7	SOP "deviations" – (example)	11.K (8)
11.L	Reworking	
11.L.1	Reworking rejected products	11.L (1)
11.L.2	Reworking of products that have not been rejected	11.L (4)
11.M	Warehouse and logistics	
11.M.1	Stock management system	11.M (1)
11.M.1.1	<i>Responsibilities</i>	11.M (1)
11.M.1.2	<i>Personnel</i>	11.M (2)
11.M.1.3	<i>Controlling the turnover of materials</i>	11.M (2)
11.M.1.4	<i>Warehouse organisation</i>	11.M (3)
11.M.2	Storage areas	11.M (4)
11.M.2.1	<i>Size</i>	11.M (4)
11.M.2.2	<i>Illumination</i>	11.M (4)
11.M.2.3	<i>Incoming goods and dispatch</i>	11.M (5)
11.M.2.4	<i>Sampling</i>	11.M (5)
11.M.2.5	<i>Quarantine</i>	11.M (6)
11.M.2.6	<i>Other storage areas</i>	11.M (7)
11.M.3	Storage conditions	11.M (8)
11.M.3.1	<i>Temperature and humidity</i>	11.M (8)
11.M.3.2	<i>Sanitation</i>	11.M (10)
11.M.4	Receipt	11.M (11)
11.M.5	Identification using material and batch number	11.M (15)
11.M.6	Dispatch and transport	11.M (16)

## 12 Sterile Production

## 13 Packaging

13.A	Packaging material	
13.A.1	Responsibilities	13.A (2)
13.A.2	Contents	13.A (2)
13.A.3	Materials	13.A (2)
13.A.4	Protection against counterfeit medicinal products	13.A (6)
13.A.5	Packaging material testing	13.A (7)
13.A.5.1	<i>Control tests carried out at the supplier</i>	13.A (7)
13.A.5.2	<i>Examples</i>	13.A (8)
13.A.5.3	<i>Defect evaluation lists</i>	13.A (9)
13.A.5.4	<i>Storage</i>	13.A (11)

13.A.5.5	Labelling	13.A (12)
13.B	Packaging process	
13.B.1	Allocation of packaging material	13.B (2)
13.B.2	Line clearance	13.B (3)
13.B.3	Labelling	13.B (6)
13.B.4	Control functions	13.B (6)
13.B.5	Release for production	13.B (8)
13.B.6	In-process controls	13.B (15)
13.B.6.1	Organisation	13.B (15)
13.B.6.2	Function inspections	13.B (18)
13.B.6.3	Checking (partially) packed goods	13.B (20)
13.B.7	Cleaning primary containers	13.B (21)
13.B.8	Labelling	13.B (21)
13.B.9	Variable data	13.B (22)
13.B.10	Imprints	13.B (23)
13.B.11	Reconciliation	13.B (24)
13.B.12	Safety features	13.B (26)
13.B.13	Completion of a packaging process	13.B (26)
13.C	Qualification of a packaging line	
13.C.1	Master qualification plan	13.C (2)
13.C.2	Design qualification (DQ)	13.C (11)
13.C.2.1	Design qualification protocol	13.C (11)
13.C.2.2	Design qualification report	13.C (14)
13.C.3	Installation qualification (IQ)	13.C (28)
13.C.3.1	Installation qualification protocol	13.C (28)
13.C.3.2	Installation qualification report	13.C (33)
13.C.4	Operational qualification (OQ)	13.C (41)
13.C.4.1	Operational qualification protocol	13.C (41)
13.C.4.2	Operational qualification report	13.C (47)
13.C.5	Performance qualification (PQ)	13.C (55)
13.C.5.1	Performance qualification protocol	13.C (55)
13.C.5.2	Performance qualification report	13.C (59)

## 14 Quality Control

14.A	Sampling	
14.A.1	Requirements	14.A (2)
14.A.1.1	Personnel	14.A (2)
14.A.1.2	Equipment	14.A (2)
14.A.1.3	Containers	14.A (2)
14.A.1.4	Premises	14.A (3)
14.A.2	Sampling plan (instructions)	14.A (3)
14.A.3	Notes for the sampling process	14.A (5)

14.A.3.1	Containers and identification labelling	14.A (5)
14.A.3.2	Sampling report	14.A (5)
14.A.3.3	Reference samples	14.A (8)
<b>14.B</b>	<b>Reagents</b>	
14.B.1	Labelling	14.B (2)
14.B.2	Usage and stability	14.B (2)
14.B.3	Documentation	14.B (3)
<b>14.C</b>	<b>Standards and reference substances</b>	
14.C.1	Definition of different standards and their areas of use	14.C (1)
14.C.2	Handling, storage and stability	14.C (4)
<b>14.D</b>	<b>Qualifying laboratory instruments</b>	
14.D.1	Qualification protocols and reports	14.D (2)
14.D.1.1	Design qualification (DQ)	14.D (2)
14.D.1.2	Installation qualification (IQ)	14.D (3)
14.D.1.3	Operational qualification (OQ)	14.D (4)
14.D.1.4	Performance qualification (PQ)	14.D (4)
14.D.2	System suitability test (SST)	14.D (5)
<b>14.E</b>	<b>Calibration in the lab</b>	
14.E.1	Definitions	14.E (1)
14.E.1.1	Persons	14.E (1)
14.E.1.2	Instruments	14.E (1)
14.E.1.3	Working	14.E (2)
14.E.2	Calibration instructions and record	14.E (2)
14.E.2.1	Test intervals, test points, test instructions	14.E (3)
14.E.3	Examples	14.E (3)
14.E.3.1	Balance	14.E (3)
14.E.3.2	Volume measuring instruments	14.E (5)
14.E.3.3	Photometer	14.E (7)
14.E.3.4	HPLC system	14.E (9)
14.E.4	Decision	14.E (18)
14.E.4.1	Requirements, tolerances, specifications	14.E (18)
14.E.4.2	Equipment release	14.E (18)
14.E.4.3	Out of calibration	14.E (18)
<b>14.F</b>	<b>Validation of analytical methods</b>	
14.F.1	Principles	14.F (1)
14.F.2	Definitions of the parameters	14.F (2)
14.F.2.1	Precision	14.F (2)
14.F.2.2	Accuracy	14.F (3)
14.F.2.3	LOD = Limit of Detection	14.F (3)
14.F.2.4	LOQ = Limit of Quantitation	14.F (4)
14.F.2.5	Selectivity	14.F (4)

14.F.2.6	<i>Linearity, Range</i>	14.F (4)
14.F.2.7	<i>Robustness</i>	14.F (4)
<b>14.F.3</b>	<b>Documentation</b>	<b>14.F (5)</b>
<b>14.F.4</b>	<b>Revalidation</b>	<b>14.F (5)</b>
<b>14.G</b>	<b>Stability testing</b>	
<b>14.G.1</b>	<b>ICH guidelines for stability tests</b>	<b>14.G (2)</b>
<b>14.G.2</b>	<b>Storage and storage conditions</b>	<b>14.G (3)</b>
14.G.2.1	<i>Standard storage conditions</i>	14.G (3)
14.G.2.2	<i>Packaging</i>	14.G (6)
14.G.2.3	<i>Sample quantities</i>	14.G (7)
14.G.2.4	<i>Stress test</i>	14.G (7)
14.G.2.5	<i>Freeze test</i>	14.G (8)
14.G.2.6	<i>Temperature cycling test</i>	14.G (9)
14.G.2.7	<i>Special storage conditions for drug products</i>	14.G (9)
14.G.2.8	<i>Labelling</i>	14.G (11)
<b>14.G.3</b>	<b>Analyses</b>	<b>14.G (12)</b>
14.G.3.1	<i>Test parameters</i>	14.G (13)
14.G.3.2	<i>Reference samples</i>	14.G (14)
14.G.3.3	<i>Consumption test</i>	14.G (14)
14.G.3.4	<i>Compatibility test for injection solutions for infusions</i>	14.G (14)
14.G.3.5	<i>Analysis of compatibility of rubber stoppers and plastic components</i>	14.G (14)
14.G.3.6	<i>Photostability (ICH Q1B)</i>	14.G (15)
14.G.3.7	<i>Microbiological analyses</i>	14.G (17)
14.G.3.8	<i>Analysis of standing times</i>	14.G (18)
14.G.3.9	<i>Analysis of transport conditions</i>	14.G (18)
<b>14.G.4</b>	<b>Reduction of the study design</b>	<b>14.G (19)</b>
14.G.4.1	<i>Bracketing</i>	14.G (19)
14.G.4.2	<i>Matrixing</i>	14.G (20)
<b>14.G.5</b>	<b>Stability testing in the marketing phase</b>	<b>14.G (23)</b>
14.G.5.1	<i>Follow-up stability testing (FuST)</i>	14.G (23)
14.G.5.2	<i>Stability commitment (SC)</i>	14.G (24)
<b>14.G.6</b>	<b>Defining the retest period for an active pharmaceutical ingredient and the shelf life for a drug product through evaluation of stability data (ICH Q1E)</b>	<b>14.G (35)</b>
14.G.6.1	<i>Data evaluation for the retest period for APIs and shelf life for drug products that are intended for storage at room temperature</i>	14.G (35)
14.G.6.2	<i>Data evaluation for period for APIs and shelf life for drug products intended for storage in refrigerator (2–8 °C)</i>	14.G (37)

14.G.6.3	<i>Date evaluation for retest period for APIs and shelf life for drug products for intended storage in a freezer (-20 °C)</i>	14.G (37)
14.G.7	<b>Decision tree for data evaluation for retest period or for APIs or drug products (excluding frozen products)</b>	14.G (38)
14.G.8	<b>Procedure for statistical analysis</b>	14.G (38)
14.G.9	<b>Examples of the statistical evaluation of stability data</b>	14.G (38)
14.G.9.1	<i>Data analysis for a single batch</i>	14.G (38)
14.G.9.2	<i>Data analysis of one attribute in each batch for several batches of the same product (known as One-Factor, Full-Design Studies)</i>	14.G (41)
14.G.9.3	<i>Data analysis of all attributes for several batches (Multi-Factor, Full-Design Studies)</i>	14.G (41)
14.H	<b>Out-of-specification results</b>	
14.H.1	<b>Significance</b>	14.H (1)
14.H.1.1	<i>The BARR Laboratories case</i>	14.H (1)
14.H.1.2	<i>The consequences</i>	14.H (2)
14.H.2	<b>Definitions</b>	14.H (3)
14.H.3	<b>FDA Draft Guidance and Comments</b>	14.H (5)
14.H.4	<b>Example for handling of an OOS result</b>	14.H (9)
14.H.5	<b>Trend tracking</b>	14.H (16)
14.I	<b>Raw data documentation</b>	
14.I.1	<b>Principles</b>	14.I (1)
14.I.2	<b>Single sheet documentation system</b>	14.I (3)
14.I.2.1	<i>Cover sheet</i>	14.I (3)
14.I.2.2	<i>Data sheet</i>	14.I (3)
14.I.2.3	<i>Index sheet</i>	14.I (7)
14.J	<b>Batch release</b>	
14.J.1	<b>Certification by a qualified person and release in accordance with EC GMP Guidelines</b>	14.J (1)
14.J.1.1	<i>Regulations contained in Directive 2001/83/EC</i>	14.J (2)
14.J.1.2	<i>Objectives of appendix 16</i>	14.J (3)
14.J.1.3	<i>Cases of application</i>	14.J (5)
14.J.2	<b>Responsibility for issuing the release</b>	14.J (6)
14.J.3	<b>Publication of release</b>	14.J (7)
14.J.4	<b>Release procedures in practice</b>	14.J (8)
<b>15</b>	<b>Documentation</b>	
15.A	<b>Official requirements</b>	
15.A.1	<b>GMP-requirements managed and reviewed according to german pharma business regulations</b>	15.A (1)
15.A.2	<b>Requirements of the EU GMP Guideline</b>	15.A (4)

15.A.3	Formal requirements	15.A (8)
15.A.4	Management and revision documentation	15.A (12)
15.B	GMP-conforming documentation	
15.B.1	Handwritten entries	15.B (1)
15.B.2	Archiving	15.B (2)
15.B.3	Master-SOP – "GMP-conforming documentation"	15.B (3)
15.C	Batch documentation	
15.C.1	Manufacturing instructions/record	15.C (3)
15.C.1.1	<i>Manufacturing instructions</i>	15.C (3)
15.C.1.2	<i>Batch processing record</i>	15.C (4)
15.C.1.3	<i>Master of manufacturing instructions/batch processing record</i>	15.C (5)
15.C.2	Packaging instruction and batch packaging record	15.C (25)
15.C.2.1	<i>Packaging instruction</i>	15.C (25)
15.C.2.2	<i>Batch packaging record</i>	15.C (26)
15.C.3	Electronic batch recording	15.C (26)
15.C.3.1	<i>Strategic objectives of an Electronic Batch Recording System (EBRS)</i>	15.C (27)
15.C.3.2	<i>GMP aspects</i>	15.C (28)
15.C.4	Testing procedures and test protocol	15.C (29)
15.C.4.1	<i>Testing procedures</i>	15.C (29)
15.C.4.2	<i>Test protocol</i>	15.C (31)
15.C.5	Batch record review	15.C (33)
15.C.5.1	<i>Regulatory requirements</i>	15.C (33)
15.C.5.2	<i>Benefits of an independent batch record review</i>	15.C (33)
15.C.5.3	<i>Responsibility and competencies</i>	15.C (34)
15.C.5.4	<i>Scope of a batch record review</i>	15.C (34)
15.C.5.5	<i>Deviations, changes relevant to marketing authorisation, recording errors</i>	15.C (36)
15.D	Standard operating procedures (SOPs)	
15.D.1	Compilation	15.D (2)
15.D.1.1	<i>Design and format</i>	15.D (4)
15.D.1.2	<i>Identification</i>	15.D (6)
15.D.2	Approval and implementation	15.D (7)
15.D.3	Training	15.D (7)
15.D.4	Usage	15.D (8)
15.D.5	Review	15.D (8)
15.D.6	Changes	15.D (9)
15.D.7	Withdrawing an operating procedure	15.D (9)
15.D.8	Administration	15.D (10)
15.D.8.1	<i>Status identification</i>	15.D (10)
15.D.8.2	<i>Distribution</i>	15.D (10)
15.D.8.3	<i>Integration</i>	15.D (10)
15.D.8.4	<i>Use of computerised systems</i>	15.D (11)

15.D.9	Archiving	15.D (11)
15.D.10	Example of an SOP "Compilation and administration of operating procedures"	15.D (12)
15.E	Site master file	
15.E.1	Introduction	15.E (1)
15.E.2	Design	15.E (1)
15.E.2.1	<i>General information</i>	15.E (2)
15.E.2.2	<i>Personnel</i>	15.E (3)
15.E.2.3	<i>Premises and equipment</i>	15.E (3)
15.E.2.4	<i>Documentation</i>	15.E (5)
15.E.2.5	<i>Production</i>	15.E (7)
15.E.2.6	<i>Quality control</i>	15.E (8)
15.E.2.7	<i>Contract manufacturing and contract quality control</i>	15.E (8)
15.E.2.8	<i>Distribution, complaints and product recalls</i>	15.E (9)
15.E.2.9	<i>Self-inspection</i>	15.E (9)
15.E.2.10	<i>Appendix</i>	15.E (10)
15.F	Annual product review	
15.F.1	Documents required for an annual product review	15.F (3)
15.F.2	Annual product review report	15.F (4)
15.F.3	Collaboration with a contract manufacturer	15.F (6)
15.F.4	Example: annual product review	15.F (7)
15.F.5	Master-SOP for the annual product review	15.F (12)

## 16 Research and Development

## 17 Contract Manufacturing and Analysis

17.A	Contract manufacture	
17.A.1	Reasons for contract manufacture	17.A (1)
17.A.2	Procedure for assigning manufacturing contracts	17.A (3)
17.A.3	Duties of the contract giver	17.A (8)
17.A.3.1	<i>Selection of one or more contract acceptors</i>	17.A (9)
17.A.3.2	<i>Handover of the necessary documents to the contract acceptor</i>	17.A (10)
17.A.3.3	<i>Secrecy agreement</i>	17.A (11)
17.A.3.4	<i>Carrying out an audit and approval of the contract acceptor</i>	17.A (11)
17.A.3.5	<i>Approval of manufacturing instructions</i>	17.A (11)
17.A.4	Duties of the contract acceptor	17.A (11)
17.A.4.1	<i>Flexibility of a contract acceptor</i>	17.A (12)
17.A.4.2	<i>Full-service contract acceptor</i>	17.A (12)
17.A.4.3	<i>Procurement and testing of starting materials</i>	17.A (12)
17.A.4.4	<i>Analysis of products manufactured under contract</i>	17.A (13)

17.A.4.5	<i>Implementation of the contract giver's requirements</i>	17.A (15)
17.A.4.6	<i>Manufacture and analysis in accordance with the relevant instructions from the contract giver</i>	17.A (15)
17.A.4.7	<i>Existence of quality assurance activities</i>	17.A (16)
<b>17.A.5</b>	<b>Contract manufacturer agreement</b>	<b>17.A (16)</b>
17.A.5.1	<i>Legal principles</i>	17.A (17)
17.A.5.2	<i>Minimum requirements</i>	17.A (17)
17.A.5.3	<i>Compilation of a secrecy agreement</i>	17.A (19)
17.A.5.4	<i>Time needed</i>	17.A (19)
17.A.5.5	<i>Contract manufacturer agreements for audits</i>	17.A (19)
<b>17.A.6</b>	<b>Audits of contract manufacturers</b>	<b>17.A (20)</b>
17.A.6.1	<i>Frequency of audits</i>	17.A (20)
17.A.6.2	<i>Types of audits</i>	17.A (21)
17.A.6.3	<i>Main audit priorities</i>	17.A (22)
17.A.6.4	<i>Result of an audit</i>	17.A (22)
17.A.6.5	<i>How does a contract acceptor prepare for an audit?</i>	17.A (27)
17.A.6.6	<i>Carrying out follow-up audits</i>	17.A (27)
17.A.6.7	<i>Positive spin offs of audits</i>	17.A (27)
<b>17.A.7</b>	<b>SOP for assigning manufacturing contracts</b>	<b>17.A (28)</b>
<b>17.A.8</b>	<b>Framework contract for contract manufacture and quality control</b>	<b>17.A (34)</b>
<b>17.B</b>	<b>Contract Analysis</b>	
17.B.1	<b>Introduction</b>	17.B (1)
17.B.2	<b>Legal basis</b>	17.B (1)
17.B.3	<b>Selection of a suitable external testing laboratory</b>	17.B (3)
17.B.4	<b>Sequence of external contracting</b>	17.B (3)
17.B.5	<b>Liability limitation contract</b>	17.B (4)
17.B.5.1	<i>Sample contract for contract analysis</i>	17.B (6)
17.B.6	<b>Questions that emerge in practise</b>	17.B (9)
17.B.6.1	<i>Test procedure – who is responsible for what?</i>	17.B (9)
17.B.6.2	<i>Questions of liability</i>	17.B (9)
17.B.6.3	<i>Test certificates containing evaluations</i>	17.B (10)
17.B.6.4	<i>Typical errors</i>	17.B (11)
<b>18</b>	<b>Inspections</b>	
18.A	<b>Principles</b>	
18.B	<b>Inspection procedures</b>	
18.B.1	<b>System-based</b>	18.B (1)
18.B.2	<b>Product-based</b>	18.B (2)
18.B.3	<b>Procedure-based</b>	18.B (2)
18.B.4	<b>Area-based</b>	18.B (3)

18.C	Inspectors	
18.C.1	Technical qualification requirements	18.C (1)
18.C.2	Personal requirements	18.C (3)
18.D	Organisation of inspections	
18.D.1	Inspection planning	18.D (1)
18.D.2	Inspection preparation	18.D (3)
18.D.3	Carrying out the inspections	18.D (4)
18.D.3.1	<i>Opening discussion</i>	18.D (4)
18.D.3.2	<i>Site inspection</i>	18.D (5)
18.D.3.3	<i>Documentation check</i>	18.D (6)
18.D.3.4	<i>Concluding discussion</i>	18.D (7)
18.D.4	Evaluation and documentation	18.D (8)
18.E	Self-inspection	
18.E.1	Purpose of self-inspection	18.E (1)
18.E.2	Carrying out the self-inspection	18.E (1)
18.E.3	Self-inspection documentation	18.E (3)
18.E.4	Errors and remedial action	18.E (9)
18.E.5	Follow-up activities	18.E (12)
18.F	Inspection of contract manufacturers	
18.F.1	Purpose of the inspection of contract manufacturer	18.F (1)
18.F.2	Carrying out inspections of contract manufacturer	18.F (1)
18.F.3	Handling of changes and deviations	18.F (3)
18.G	Inspection of suppliers	
18.G.1	Purpose of the supplier inspection	18.G (1)
18.G.2	Carrying out the supplier inspection	18.G (2)
18.H	Questionnaire for preparing GMP-inspections	
18.I	Supplier qualification	
18.I.1	Suppliers (traders) and manufacturers of raw materials	18.I (1)
18.I.2	Selection of manufacturer or supplier	18.I (3)
18.I.3	Audit of active pharmaceutical ingredient manufacturers	18.I (4)
18.I.3.1	<i>Preparation</i>	18.I (5)
18.I.3.2	<i>Type of inspection</i>	18.I (14)
18.I.3.3	<i>Questions for opening discussion</i>	18.I (15)
18.I.3.4	<i>Inspection sequence: Documents versus site visit</i>	18.I (16)
18.I.3.5	<i>Inspection questionnaire</i>	18.I (16)
18.I.3.6	<i>Change of supplier</i>	18.I (27)
18.I.3.7	<i>Suppliers of packaging materials</i>	18.I (28)

<b>19</b>	<b>Tools for Quality Assurance</b>	
19.A	Project management	
19.A.1	Definition of project and project management	19.A (1)
19.A.2	Project sequence	19.A (2)
19.A.2.1	<i>Project planning</i>	19.A (2)
19.A.2.2	<i>Project controlling</i>	19.A (2)
19.A.2.3	<i>Project conclusion</i>	19.A (2)
19.A.3	Project organisational structure	19.A (3)
19.A.3.1	<i>Project manager</i>	19.A (4)
19.A.3.2	<i>Project team</i>	19.A (4)
19.A.3.3	<i>Steering team</i>	19.A (5)
19.A.4	Project phases	19.A (5)
19.A.4.1	<i>Project start</i>	19.A (5)
19.A.4.2	<i>Project implementation</i>	19.A (5)
19.A.4.3	<i>Project conclusion</i>	19.A (6)
19.A.5	Aids	19.A (6)
19.A.6	Multi-project organisation	19.A (9)
19.A.6.1	<i>Project classes</i>	19.A (9)
19.A.6.2	<i>Project priorities</i>	19.A (9)
19.A.6.3	<i>Management information</i>	19.A (9)
19.A.7	Frequently occurring problems in the context of project management	19.A (10)
19.B	Risk analysis	
19.B.1	Development of the risk analysis	19.B (1)
19.B.2	FMEA – Failure Mode and Effects Analysis	19.B (4)
19.B.2.1	<i>Development</i>	19.B (4)
19.B.2.2	<i>Procedure during FMEA</i>	19.B (4)
19.B.2.3	<i>Failure finding</i>	19.B (5)
19.B.2.4	<i>Failure evaluation</i>	19.B (9)
19.B.2.5	<i>Measures to eliminate failures</i>	19.B (11)
19.B.3	Introduction of a GMP risk analysis according to FMEA method	19.B (13)
19.B.3.1	<i>Advantages</i>	19.B (13)
19.B.3.2	<i>Disadvantages</i>	19.B (16)
19.B.4	Company-specific risk analysis	19.B (26)
19.B.4.1	<i>Advantages</i>	19.B (26)
19.B.4.2	<i>Disadvantages</i>	19.B (27)
19.B.4.3	<i>Procedure</i>	19.B (28)
19.B.4.4	<i>Example</i>	19.B (28)
19.B.5	Hazard Analysis of Critical Control Points	19.B (37)
19.B.5.1	<i>Failure finding</i>	19.B (39)
19.B.5.2	<i>Evaluation of problem points</i>	19.B (40)
19.B.5.3	<i>Definition of measures</i>	19.B (40)

19.B.5.4	Documentation	19.B (41)
19.B.5.5	HACCP summary	19.B (42)
19.C	Change control	
19.C.1	Principles of change control	19.C (1)
19.C.2	Introduction and operation of change control programs	19.C (4)
19.C.3	Documentation	19.C (9)
<b>20</b>	<b>Active Pharmaceutical Ingredient (API) Production</b>	
<b>21</b>	<b>References</b>	

# File 4 to 5

- A**        **Index file 4 to 5**
  
- B**        **Information**
  - B.1        List of Abbreviations
  - B.2        Glossary
  - B.3        Adress-Register
  
- C**        **EU GMP Guide**
  - C.1        Introduction
  - C.2        Commission Directive 2003/94/EC
  - C.3        Directive 91/412/EEC
  - C.4        Part I
    - Basic Requirements for Medicinal Products
  - C.5        Part II
    - Basic Requirements for Active Substances used as Starting Materials
  - C.6.1      Annex 1
    - Manufacture of Sterile Medicinal Products
  - C.6.2      Annex 2
    - Manufacture of Biological Medicinal Products for Human Use
  - C.6.3      Annex 3
    - Manufacture of Radiopharmaceuticals
  - C.6.4      Annex 4
    - Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products
  - C.6.5      Annex 5
    - Manufacture of Immunological Veterinary Medicinal Products
  - C.6.6      Annex 6
    - Manufacture of medicinal gases
  - C.6.7      Annex 7
    - Manufacture of Herbal Medicinal Products
  - C.6.8      Annex 8
    - Sampling of Starting and Packaging Materials

- C.6.9 Annex 9  
Manufacture of Liquids, Creams and Ointments
- C.6.10 Annex 10  
Manufacture of Pressurised Metered Dose Aerosol  
Preparations for Inhalation
- C.6.11 Annex 11  
Computerised Systems
- C.6.12 Annex 12  
Use of Ionising Radiation in the Manufacture of Medicinal  
Products
- C.6.13 Annex 13 – Revision 1  
Manufacture of Investigational Medicinal Products
- C.6.14 Annex 14 – Revision  
Manufacture of medicinal Products derived from human  
Blood or Plasma
- C.6.15 Annex 15  
Final Version – Qualification and validation
- C.6.16 Annex 16  
Final Version: Certification by a Qualified Person and Batch  
Release
- C.6.17 Annex 17  
Final version – Parametric Release
- C.6.18 Annex 18  
Final version – Good Manufacturing Practice for Active  
Pharmaceutical Ingredients
- C.6.19 Annex 19  
Reference Samples and Retention Samples
- C.7 Glossary
- C.8 Index EU GMP Guide  
C.1 to C.6.19
- C.9 Note For Guidance on Quality of Water for Pharmaceutical  
Use
- C.9 Index C.9
  
- D USA: CFR and FDA Guidelines**
- D.1 21 CFR Part 210  
Current good manufacturing practice in manufacturing,  
processing, packing, or holding of drugs
- D.1 21 CFR Part 211  
Current Good Manufacturing Practice for Finished  
Pharmaceuticals

- D.1 21 CFR Part 11
  - Electronic records; electronic signature
- D.1 Index chapter D.1
- D.2 Guideline on General Principles of Process Validation
  - D.2 Index chapter D.2
- D.3 Guide to Inspections of High Purity Water Systems
  - D.3 Index chapter D.3
- D.4 Guide to Inspections of Validation of Cleaning Processes
  - D.4 Index chapter D.4
- D.5 Guide to inspections of oral solid dosage forms pre/post approval issues for development and validation
  - D.5 Index chapter D.5
- D.6 Guide to Inspections of Validation Documentation
  - D.6 Index chapter D.6
- D.7 Guide to Inspection of Computerized Systems in Drug Processing
  - D.7 Index chapter D.7
- D.8 Guide to Inspections of Pharmaceutical Quality Control Laboratories
  - D.8 Index chapter D.8
- D.9 Guidance for Industry: investigating out of specification (OOS) test results for pharmaceutical production
  - D.9 Index chapter D.9
- D.10 Guidance for Industry Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice
  - D.10 Index chapter D.10
- D.11 Guidance for Industry PAT –A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance
  - D.11 Index chapter D.11
  
- E ICH-Guidelines**
- E.1 ICH Q1A Stability Testing of New Drug Substances And Products
  - E.1 Index chapter E.1
- E.2 ICH Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products
  - E.2 Index chapter E.2
- E.3 ICH Q1C: Stability Testing: Requirements for New Dosage Forms

- E.4 Guideline for Industry: Q2A Text on Validation of Analytical Procedures: Definitions and Terminology
- E.4 Index chapter E.4
- E.5 Guidance for Industry: Q2B Validation of Analytical Procedures: Methodology
- E.5 Index chapter E.5
- E.6 ICH Q7A: Good Manufacturing Practice for Active Pharmaceutical Ingredients
- E.6 Index chapter E.6
- E.7 ICH Q8: Pharmaceutical Development
- E.8 ICH Q9: Quality Risk Management
- E.8 Index chapter E.8

## **F PIC/S Guidelines**

- F.1 Recommendations on Validation Master Plan Installation and Operational Qualification Non-Sterile Process Validation Cleaning Validation (PIC/S PI 006)
- F.1 Index chapter F.1
- F.2 Recommendations on the Validation of Aseptic Processes (PIC/S PI 007)
- F.2 Index chapter F.2
- F.3 PIC/S Guidance Good Practices for Computerised Systems in Regulated “GXP” Environments (PIC/S PI 011)
- F.3 Index chapter F.3

## **G WHO Guidelines**

- G.1 Guide to good storage practices for pharmaceuticals
- G.1 Index chapter G.1

## **H Empty Register**