MANUAL

Compliance Management System Manual

This manual describes how the compliance management system of [Company Name] meets, clause by clause, the requirements of ISO 37301:2021. It provides the top-level description of the system and the traceability between the standard and the organisation's policies, procedures, work instructions, forms and records.

DOCUMENT NO	REVISION	EFFECTIVE DATE	OWNER
MAN-01	[Revision]	[Date]	[Designation Here]

3.1 Scope of the compliance management system

The CMS applies to the compliance obligations arising from all activities, products and services of [Company Name]: the manufacture, distribution, promotion and sale of medicines and related products, and the corporate functions that support them. It covers all sites (the headquarters, the two manufacturing plants and the three distribution centres), all functions, and all personnel, together with third parties acting on the organisation's behalf so far as their conduct bears on the organisation's compliance obligations. The scope was determined by considering the external and internal issues, the needs and expectations of interested parties, the compliance obligations, and the compliance risk assessment, in accordance with clause 4.3, and is maintained as documented information in the CMS Scope Statement (QF-01-03).

No requirement of ISO 37301:2021 is excluded from the CMS. All of clauses 4 to 10 are applicable to the organisation and are addressed in this manual.

The scope is deliberately drawn to include the organisation's most significant compliance exposures. In manufacturing, these centre on Good Manufacturing Practice, product licensing and the integrity of the quality system. In distribution, they centre on Good Distribution Practice, the control of the supply chain, and the handling of controlled substances. In the commercial and medical-affairs division, they centre on anti-bribery in interactions with healthcare professionals, adherence to promotional and advertising codes, and the protection of patient and healthcare-professional data. Across the whole organisation they include pharmacovigilance, product safety and recall, trade and competition law, and employment and safety obligations. By bringing all of these within a single compliance management system, the organisation is able to manage them consistently, to see the connections between them, and to demonstrate control of the whole compliance landscape rather than of isolated parts of it.

3.2 Normative references

ISO 37301:2021 contains no normative references. For information and good practice the organisation refers, where useful, to ISO 31000 for risk management, ISO 37001 for anti-bribery management, ISO 19011 for auditing management systems, and to the applicable pharmaceutical good-practice guidelines; these are used for guidance only and do not add requirements to the CMS.

3.3 Terms and definitions

The terms used in this manual carry the meanings given in ISO 37301:2021, Clause 3. The following are used frequently: compliance obligation (a requirement the organisation has to or chooses to comply with); compliance risk (the effect of uncertainty on compliance objectives); compliance culture; the compliance function (the person or group with responsibility and authority for the operation of the CMS); the governing body (the person or group with ultimate accountability); top management; management; and interested party. Abbreviations used include CMS (compliance management system), GMP (Good

PROCEDURE

Compliance Obligations Identification and Evaluation

This procedure defines how [Company Name] systematically identifies its compliance obligations, assesses their impact on its operations, identifies new and changed obligations, evaluates the impact of changes, and maintains the compliance obligations register as documented information. It gives effect to ISO 37301:2021 clause 4.5.

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QP-02	[Revision]	[Date]	[Designation Here]

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Reviewed by	[Name], [Designation Here]
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Revision History

Version	Date	Description of change	Author	Approved
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Contents

PROCEDURE

Compliance Obligations Identification and Evaluation

How the organisation finds, records, keeps current and evaluates the impact of the obligations it must and chooses to comply with.

1 Purpose

The purpose of this procedure is to ensure that [Company Name] knows, at all times, the full set of compliance obligations arising from its activities, products and services, understands the impact of each on its operations, and keeps that knowledge current as obligations change. In a pharmaceutical group the obligations are numerous, technical and fast-moving, spanning product licensing, manufacturing and distribution quality, pharmacovigilance, controlled substances, anti-bribery in dealings with healthcare professionals, promotional codes, data protection, trade controls and more. A complete and current obligations register is the single most important input to the compliance risk assessment and to the design of controls, and it is the reference against which the organisation demonstrates that it has identified what it must comply with.

The procedure exists in particular to prevent two failures: an incomplete register that omits an obligation the organisation is in fact subject to, and a stale register that has not kept pace with a change in the law, a licence condition or an industry code. Both failures expose the organisation to undetected noncompliance, so the procedure combines a thorough initial identification with a continuous horizon-scanning process and a defined impact-evaluation step.

2 Scope

This procedure applies to all activities, products, services, sites and functions of the organisation, and to the obligations arising from third-party and outsourced arrangements so far as the organisation is responsible for them. It is led by the compliance function and draws on the regulatory affairs, legal, quality, pharmacovigilance, commercial, trade-compliance, human-resources and data-protection functions as the owners of particular obligation categories. It covers legal and regulatory obligations, licence and permit conditions, industry codes the organisation adopts, and contractual and voluntary commitments the organisation decides to meet. It uses the context and interested-party outputs of QP-01 as inputs and feeds the obligations register into QP-03.

3 References

ISO 37301:2021 clause 4.5; QP-01 Context, Interested Parties and CMS Scope; QP-03 Compliance Risk Assessment; QP-06 Planning, Objectives and Change; QP-08 Compliance Training and Awareness; QP-11 Operational Controls and Third-Party Control; WI-02-01 Regulatory Horizon Scanning; T-02 Compliance Obligations Register; forms QF-02-01 Compliance Obligations Register, QF-02-02 Obligations Horizon-Scanning and Change Log, QF-02-03 Obligation Impact Evaluation Record. These references provide supplementary information; the criteria needed to perform this procedure are contained within it, which is self-contained for the identification, recording and evaluation of obligations.

Responsibilities (RACI)

Role	Responsibility & authority	R/A/C/I
Head of Compliance	Owns this procedure; approves the obligations register and material changes	A
Compliance function	Coordinates identification, maintains the register, runs the change log and impact evaluations	R
Obligation-category owners (regulatory, quality, pharmacovigilance, legal, trade, data protection, HR)	Identify obligations in their category, monitor for changes, and evaluate impact	R
Regulatory affairs / Legal	Provide authoritative interpretation of legal and licence obligations	C
Top management	Ensures resources for the activity; informed of material new obligations	A
Function heads and site managers	Informed of obligations applying to their areas and of changes	I

5 Definitions and classification

A compliance obligation is a requirement that the organisation has to comply with, such as a law, regulation or licence condition, together with a requirement that the organisation chooses to comply with, such as an industry code or a voluntary commitment, once it has decided to adopt it. The source of an obligation is the instrument from which it arises. The owner of an obligation is the role responsible for monitoring it and ensuring it is met. The impact of an obligation is the effect that meeting it, or failing to meet it, has on the organisation's operations.

Obligations are classified in three ways so that they can be managed systematically. By category, using the compliance obligations landscape at Annex G of the manual: product licensing; manufacturing and distribution quality; pharmacovigilance; controlled substances; anti-bribery and healthcare-professional engagement; promotion and advertising; data protection; trade and competition; and people and safety.

ANNEX A

Clause Coverage

This annex maps each ISO 37301:2021 requirement owned by this document to the section that satisfies it.

Clause	Requirement (summary)	Where satisfied
4.5	Systematically identify compliance obligations and assess their impact	Steps 2 and 3; QF-02-01
4.5 a)	Process to identify new and changed obligations to ensure ongoing compliance	Step 4; WI-02-01; QF-02-02
4.5 b)	Evaluate the impact of changes and implement necessary changes	Step 5; QF-02-03
4.5	Maintain documented information of compliance obligations	Step 6; QF-02-01; T-02

This documentation toolkit was developed by the consultant panel of isofolder.

FORM

Compliance Obligations Register

Associated procedure: QP-02 Compliance Obligations Identification and Evaluation · [Company Name]

QF-02-01

REVISION **[Revision]**

ISSUE DATE **[Date]**

The master register of compliance obligations (ISO 37301:2021 clause 4.5). One row per obligation. Reviewed at least quarterly. The live version is maintained in tool T-02.

1 REGISTER DETAILS

REGISTER OWNER	**REVIEW DATE** [Date]
NEXT QUARTERLY REVIEW [Date]	**VERSION** [Revision]

2 OBLIGATIONS

Ref	Obligation	Source	Category	Owner	Status	Controls / records

APPROVAL

Role	Name	Signature	Date
Completed by	[Name]		[Date]
Reviewed by	[Name]		[Date]
Approved by	[Name]		[Date]

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FORM

Compliance Obligations Register

Associated procedure: QP-02 Compliance Obligations Identification and Evaluation · [Company Name]

QF-02-01

REVISION **[Revision]**

ISSUE DATE **[Date]**

The master register of compliance obligations (ISO 37301:2021 clause 4.5). One row per obligation. Reviewed at least quarterly. The live version is maintained in tool T-02.

1 REGISTER DETAILS

REGISTER OWNER
Compliance function

REVIEW DATE
20 March 2026

NEXT QUARTERLY REVIEW
June 2026

VERSION
5.0

2 OBLIGATIONS

Ref	Obligation	Source	Category	Owner	Status	Controls / records
OB-014	Hold and maintain marketing authorisations for all marketed products	Medicines law / MA conditions	Product licensing	Regulatory Affairs	Current	Licence register; variation procedure
OB-027	Report adverse events within statutory timelines	Pharmacovigilance legislation	Pharmacovigilance	PV Lead	Current	PV system; QF-15 reporting; KPI
OB-033	Manufacture under GMP	GMP regulations / licence	Manufacturing quality	Plant QA	Current	QMS; GMP audits; batch records
OB-041	Engage HCPs only within the promotional code and anti-bribery rules	Promotional code; anti-bribery law	Anti-bribery / HCP	Commercial Compliance	Current	Pre-approval control (QF-11); training; ToV disclosure
OB-052	Disclose transfers of value to HCPs	Amended promotional code	Promotion	Commercial Compliance	Pending (effective 1 Jul 2026)	New disclosure control; field training in progress
OB-061	Protect patient and HCP personal data	Data-protection law	Data protection	DPO	Current	DPIAs; access controls; retention schedule

APPROVAL

Role	Name	Signature	Date
Completed by	[Name]		[Date]
Reviewed by	[Name]		[Date]
Approved by	[Name]		[Date]

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FORM

Concern and Whistleblowing Report

Associated procedure: QP-12 Raising Concerns · [Company Name]

QF-12-01

REVISION **[Revision]**

ISSUE DATE **[Date]**

Confidential. Records a raised compliance concern. May be completed by the reporter or by the person receiving the concern. Anonymous reports are accepted.

1 CONCERN

REFERENCE	DATE RECEIVED
	[Date]
RECEIVED VIA	**RECEIVED BY**

WHAT IS THE CONCERN? (WHAT, WHEN, WHERE, WHO IS SAID TO BE INVOLVED)

2 REPORTER (OPTIONAL; LEAVE BLANK IF ANONYMOUS)

NAME	CONTACT
CONSENT TO BE CONTACTED	**CONSENT TO SHARE IDENTITY IF NEEDED**

3 IMMEDIATE HANDLING

CONFIDENTIALITY APPLIED ☐ Yes

NON-RETALIATION ASSESSMENT OPENED (IF IDENTIFIABLE) ☐ Yes ☐ N/A - anonymous

ACKNOWLEDGEMENT

APPROVAL

Role	Name	Signature	Date
Recorded by			[Date]

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