

Workshop - Mercoledì 10 giugno

Risk-based thinking come vera intelligenza per il mondo farmaceutico

Moderatori

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Workshop schedule

2

10:10 – 10:40 **La nuova era dell'intelligenza del rischio**

10:40 - 11:10 Nuova ICH Q1: product intelligence per un approccio innovativo alla stabilità

11:10 – 11:35 ICH Q3E: approccio risk-based integrato per la valutazione di E&L

11:35 – 12:00 Il dato come bussola: l'analisi statistica a supporto del rischio

12:00 – 12:25 Dalla teoria alla pratica: dalla gestione dello studio di stabilità all'analisi dei dati

12:25 – 12:30 Conclusione dei lavori



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The new «era» for risk-based thinking and risk intelligence

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Contents

#1 – Introduction: are we still talking about risk?

#2 – Revision expected in 2026

#3 – Workshop overview



Introduction: are we still talking about risk?

Any new definition?

Risk Definition

Combination of the probability of **Occurrence (O)** of harm and the **Severity (S)** of that harm.

$$Risk = f\{o;s\}$$

Harm

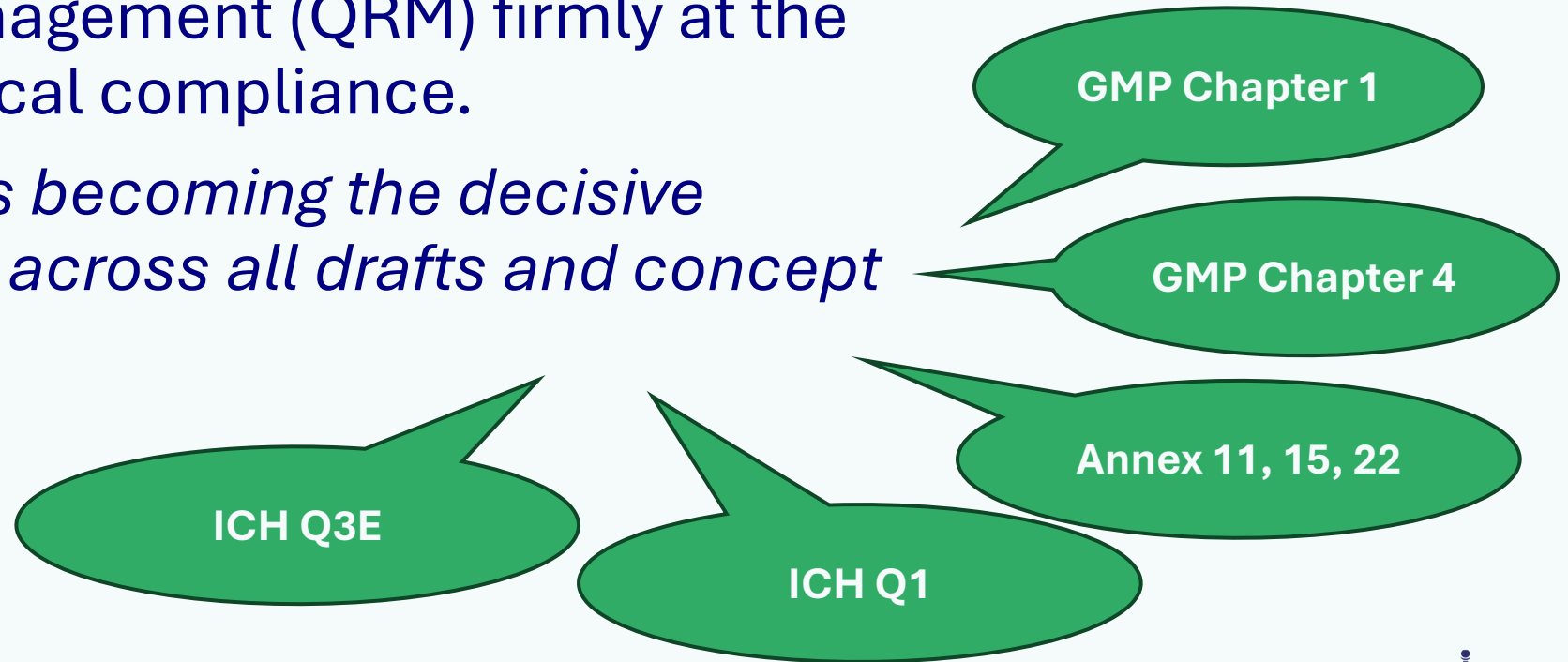
Cause

Effect



The expectation ...

- The current revisions of the EU GMP Guidelines place Quality Risk Management (QRM) firmly at the centre of pharmaceutical compliance.
- *Risk-based thinking is becoming the decisive regulatory expectation across all drafts and concept papers.*



... and the reason why



RISK IS THE ENABLER TO INFORMED AND OBJECTIVE DECISION

Let's stress the difference between:

RIGHT DECISION

something that can not be evaluated until the project end

CORRECT DECISION

best decision you can take with the objective and consistent data you have in your hands



PROCESS UNDERSTANDING ALLOW

to transform Technical information into **Quality and Business** decision

CLEAR COMMUNICATION

through different level of knowledge



Revision expected in 2026

Eudralex Vol. 4 GMP Chapter 1 «Pharmaceutical Quality System» (I/II)

- The revised Chapter 1 reflects the updated ICH guideline on Quality Risk Management, ICH Q9(R1), strengthening **knowledge management** and **risk management** across the **product lifecycle**.
- Alignment with ICH Q9(R1) fosters a **proactive, evidence-based culture that reduces variability in quality outcomes**. By embedding risk-based decision-making and emphasising scientific rationale and proportionality in risk assessment, it ensures consistent product quality and availability.



Eudralex Vol. 4 GMP Chapter 1 «Pharmaceutical Quality System» (I/II)

- The revision also stresses the importance of **proactive identification of manufacturing risks to prevent shortages** and mitigate supply chain vulnerabilities, thereby safeguarding patient safety and public health.
- The guideline also clarifies requirements for **product quality review**, particularly regarding product grouping and situations where only a limited number of batches were manufactured during the review period.



Chapter 1 Product Quality Review

Data evidence and risk evidence represent the key element to ensure product quality.

18 Trending data from the previous product quality review should be included in cases
19 where few batches of a product were manufactured in a 12-month review period. This
20 ensures that a more extensive set of data is used to assess the consistency of the process.
21 In cases where a larger number of batches of a product is manufactured in a 12-month
22 review period, it can also be useful to include trending data from the previous product
23 quality review.

24 In cases where no batches of a product were manufactured during the 12-month review
25 period, the product quality review should still be performed; this should address at least
26 the following: stability results, returns, complaints, recalls, relevant deviations
27 (including those arising from qualification and validation activities) and regulatory
28 background (e.g. marketing authorisation variations submitted, granted or refused,
29 including those for third country (export only) dossiers, and any relevant post-
30 marketing commitments). A review of the last product quality review should also be
31 conducted.

Page 7 of 9

32 Review timeframes can be appropriately adjusted based upon manufacturing and
33 campaign duration, with adequate justification. The timeframe criteria should be
34 established in a procedure. The trending performed in the review can include results
35 gathered from the previous period to ensure its robustness.

Eudralex Vol. 4 GMP Chapter 4, Annex 11 and 22

- In light of the rapid advancement of digital technologies and the implementation of AI systems in pharmaceutical manufacturing, the update of Good Manufacturing Practice (GMP) guidelines is essential to ensure that they continue to provide clear, practical and relevant guidance for manufacturers and national competent authorities.
- The revision of GMP Annex 11 and Chapter 4, along with the introduction of a dedicated Annex 22 on Artificial Intelligence aim at supporting innovation in the manufacturing of medicines and ensuring regulatory harmonisation.

Eudralex Vol. 4 GMP Chapter 4 «Documentation»

- The term «Risk» appears 54 times in the proposed text (it is not mentioned in the original text).

79	RISK MANAGEMENT	
80	4.19.	The regulated user should adopt a risk-based approach in documentation throughout the entire
81		lifecycle of data, regardless of the technology, hybrid solution or service used and should
82		demonstrate an understanding for data criticality, data risk and data quality.
83	4.20.	Controls over the data lifecycle should be established which are commensurate with the prin-
84		ciples of quality risk management. The depth of data governance and risk management activ-
85		ities should be justified and commensurate with the risks to product quality and patient safety.
86	4.21.	Decisions on the extent of measures to ensure data integrity should be based on a documented
87		rationale and documented risk assessment taking into consideration data criticality and data
88		risk.
89	4.22.	Irrespective of processes used to generate electronic data, they must be included in the re-
90		quirements for the qualification or validation of the relevant computerised systems according
91		to Annex 11.
532	Data Risk Management	An activity to be applied throughout the lifecycle of data considering the need
533		to ensure data integrity. Risk management consists of risk identification, risk
534		assessment, risk mitigation and risk control. Risk management should link to
535		other relevant procedures (e.g. configuration and change management, man-
536		agement processes for data, business risks, etc.).
537	Data Risk Assessment	The process of evaluating the risks associated with the regulated user's data. It
538		ensures an efficient and effective approach to data integrity by considering the
539		vulnerability of data to involuntary or deliberate alteration resulting in risk-
540		based control measures.

Eudralex Vol. 4 GMP Annex 11 «Computerised Systems»

- The term «Risk» appears 37 times in the proposed text while in the old it is repeated 13 times.

68 4. Risk Management

69 4.1. *Lifecycle*. Quality Risk Management (QRM) should be applied throughout the lifecycle of
70 a computerised system considering any possible impact on product quality, patient safety or
71 data integrity.

72 4.2. *Identification and analysis*. Risks associated with the use of computerised systems in GMP
73 activities should be identified and analysed according to an established procedure. Examples
74 of risk management methods and tools can be found in ICH Q9 (R1).

75 4.3. *Appropriate validation*. The validation strategy and effort should be determined based on
76 the intended use of the system and potential risks to product quality, patient safety and data
77 integrity.

78 4.4. *Mitigation*. Where applicable, risks associated with the use of computerised systems in
79 GMP activities should be mitigated and brought down to an acceptable level, if possible, by
80 modifying processes or system design. The outcome of the risk management process should
81 result in the choice of an appropriate computerised system architecture and functionality.

Page 3 of 19

82 4.5. *Data integrity*. Quality risk management principles should be used to assess the criticality
83 of data to product quality, patient safety and data integrity, the vulnerability of data to
84 deliberate or indeliberate alteration, deletion or loss, and the likelihood of detection of such
85 actions.

Eudralex Vol. 4 GMP Annex 15 «Qualification and validation»



19 January 2026
EMA/INS/GMP/20217/2026
GMP/GDP Inspectors Working Group (GMP/GDP IWG)

Concept paper on the revision of the guidelines on Good Manufacturing Practice for medicinal products - Annex 15 - Qualification and Validation

Agreed by EMA GMP/GDP IWG	30 November 2025
Agreed by PIC/S	14 January 2026
Start of public consultation	9 February 2026
End of consultation (deadline for comments)	9 April 2026

The proposed guideline will replace:

- Eudralex Volume 4: Annex 15 Qualification and validation



- 63 The proposal will also include targeted revisions of the text to consider the ICH guideline Q9 (R1) on
64 quality risk management.
- 65 • The use of QRM in the design and validation/qualification of monitoring systems will be underlined
66 in the general section. Guidance on QRM approach will be complemented with the provision for risk
67 review activities to support validation and qualification in Annex 15. This will link with the guidance
68 provided in chapter 2 of EudraLex Volume 4, Part II.
- 69 • Annex 15 will also provide emphasis on QRM in the context of traditional process.
- 70 Other relevant topics and related changes may be considered by the drafting group during the revision
71 process, and will consult GMDP IWG, PIC/S in case required.



Workshop overview

Agenda overview

18

10:10 – 10:40 The new «era» for risk-based thinking and risk intelligence

10:40 - 11:10 New ICH Q1:
Product Intelligence for an Innovative Approach to Stability

11:10 – 11:35 ICH Q3E: integrated risk-based approach for E&L evaluation

11:35 – 12:00 Data as a Compass: Statistical Analysis for Risk Management

12:00 – 12:25 From theory to practice: from stability study management up to
data analysis

12:25 – 12:30 Workshop Conclusion and Question time

Thanks for listening

The new «era» for risk-based thinking and risk intelligence



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Any questions?

Do you need any information?

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