EMA
EUROPEAN MEDICINES AGENCY

New Pharma Legislation (NPL)

Quality and Manufacturing Stream Update

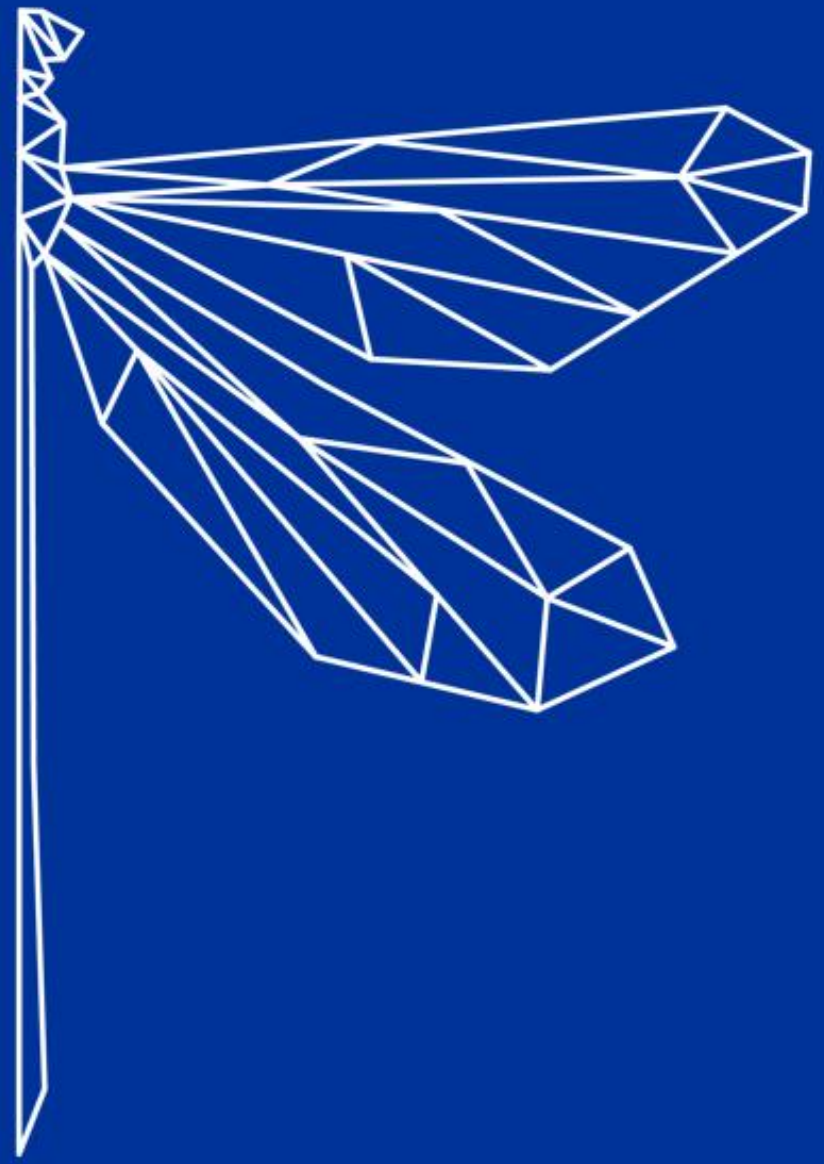
17th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

20th November 2026

Presented by Andrei Spinei

Quality and Manufacturing Stream Lead

Quality and Safety Department



Content

1. Quality and Manufacturing Stream – Road Map

2. Focus on ASMF

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Quality and Manufacturing Delivery Stream - Projects

Active Substance Master Files (ASMFs)

(DIR Art. 26)

Additional Quality Master Files (PTMFs)

(DIR Art. 27)

Platform Technologies Master Files (PTMFs)

(DIR Art. 28)

Decentralised manufacturing

(DIR Art. 29)

EMA Inspectorate

(REG Art. 54 & Annex III)

GMP Surveillance and risk-based inspections

(reliance, distant assessment, risk based inspection for API, joint inspections)

(DIR Art. 191, 192, 193, REG Art 55)

Joint Audit Programme (JAP)

(mandate and expansion to GDP)

(REG Art. 56)

GMDP, GCP, PV Inspectors Working Group

(establishment as EMA working groups)

(REG Art. 148)

Quality focused – Interested party interaction via QWP/BWP IP Meeting

Inspection focused – Interested party interaction via GMDP IWG IP Meeting

Further Delegated and/or Implementing Acts

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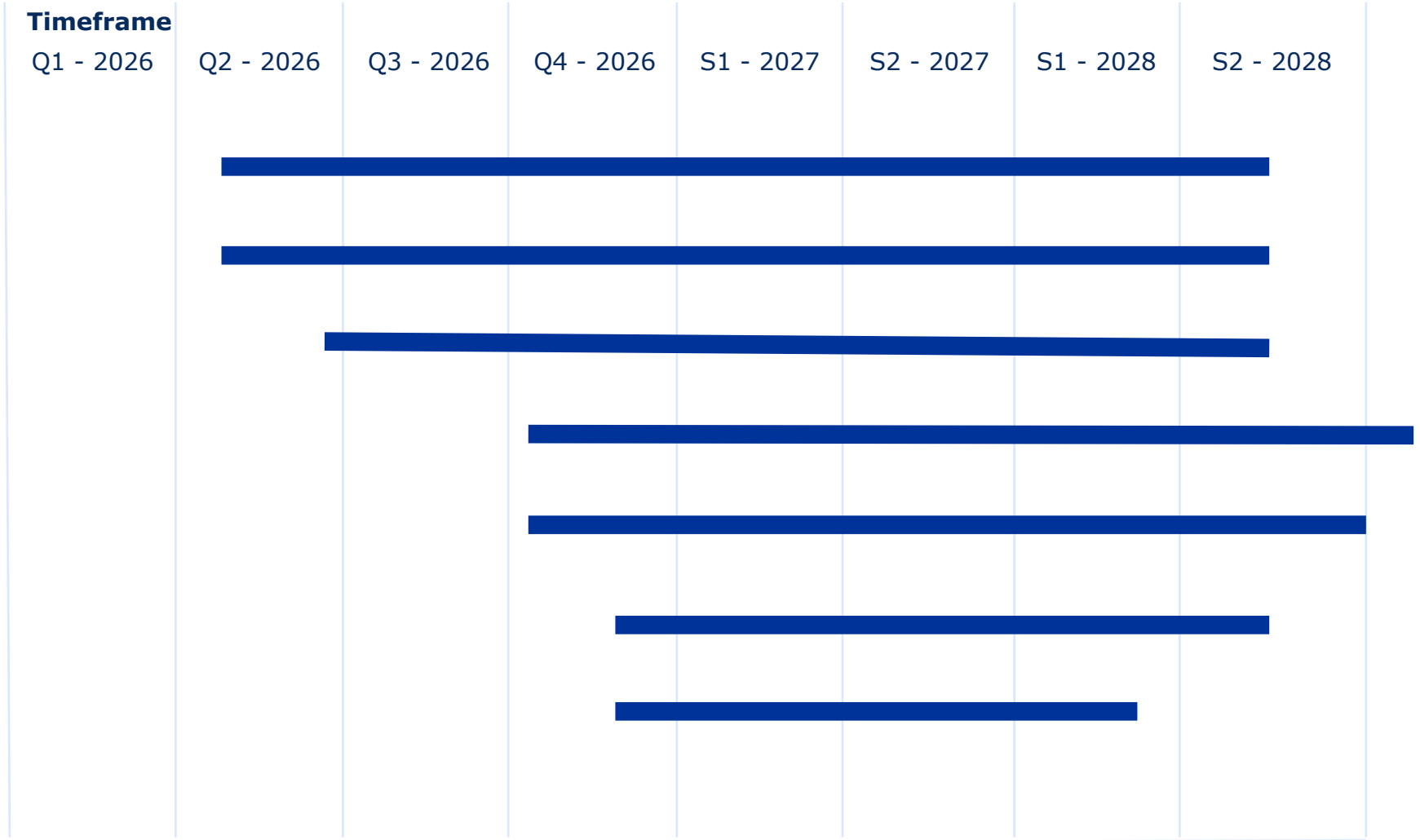
DELIVERY STREAM 4: Quality and manufacturing

4 Quality and manufacturing



Timeframe

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ASMF & AQMF Certification: Current status



Legislative text

Agreed text with official publication pending

Delegated Acts to follow



Design phase

Process kicked off under NPL governance

Currently at design phase

EU Medicines Network experts cover CAPs/NAPs, chemical and biological medicines, Working Parties and CMDh, and Working Group on Active Substance Master File Procedures



Focus

ASMF/AQMF process design

Proposed changes to Directive Annex II

Support to EC for future Delegated Acts



Stakeholder consultation

Expected during implementation, once guidance is developed, using existing consultation mechanisms

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ASMF & AQMF Certification: Guiding principles for implementation



Efficient, consistent assessment

Meet legislative requirements through a simple, proportionate framework that works for CAPs and NAPs

Based on experience with ASMF and CEP schemes

Reduce duplication, use scientific resources better and support consistent regulatory decisions



Risk-based lifecycle

Pragmatic lifecycle management based on risk



Clear pathways

Clear processes and requirements for applicants and marketing authorisation holders



Digitalisation

Digital solutions for ASMF &AQMF submission, assessment and management

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