PIC/S: TGA's Adoption Process and Future Revisions

Matt Davis
Manufacturing Quality Branch
Department of Health and Aged Care, TGA

GMP FORUM 2024

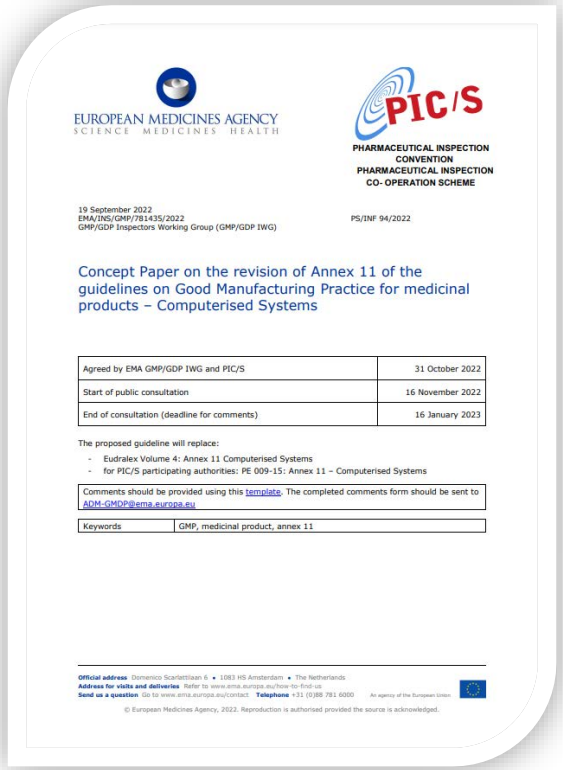
Why adopt the latest PIC/S Guide to GMP?

- Patient Safety – Product Quality
  - Mitigate risks to product quality
  - Ambiguity leading to misinterpretation and compliance risks
- International reputation
- Relevant to our Mutual Recognition Agreements
- Provides assurance of equivalence to international markets
  - Reduces regulatory burden
- Continuous Improvement

HAND GRANULATION FOR MEDICINAL TABLETS

GMP Guide Update Process

Concept paper → Consultation (General) → Draft guidance document → Consultation (PA's) → Review of comments → Final draft for approval → Adoption



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PIC/S
PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

19 September 2022
EMA/INS/GMP/781435/2022
GMP/GDP Inspectors Working Group (GMP/GDP IWG)

PS/INF 94/2022

Concept Paper on the revision of Annex 11 of the guidelines on Good Manufacturing Practice for medicinal products – Computerised Systems

Agreed by EMA GMP/GDP IWG and PIC/S	31 October 2022
Start of public consultation	16 November 2022
End of consultation (deadline for comments)	16 January 2023

The proposed guideline will replace:

- Eudralex Volume 4: Annex 11 Computerised Systems
- for PIC/S participating authorities: PE 009-15: Annex 11 – Computerised Systems

Comments should be provided using this template. The completed comments form should be sent to ADM-GMDP@ema.europa.eu

Keywords	GMP, medicinal product, annex 11

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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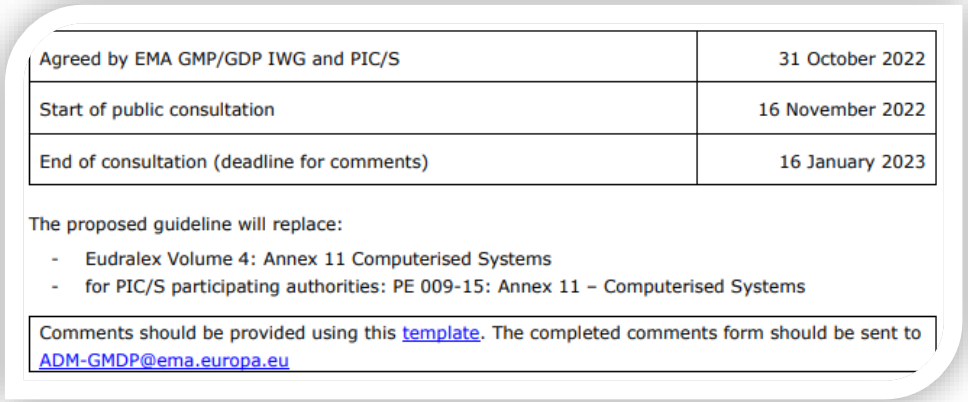
TGA



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TGA

TIWGG

Accord
Active Pharmaceutical Ingredient Manufacturer's Association of Australia (APIMAA)
Association of Therapeutic Goods Consultants Inc (ATGC)
Australia and New Zealand Region of International Society of Cell and Gene Therapy (ISCT)
Australia New Zealand Industrial Gas Association (ANZIGA)
Australian Red Cross Lifeblood (Lifeblood)
Biotherapeutics Association of Australasia (BAA)
Complementary Medicines Australia (CMA)
Consumer Healthcare Products (CHP) Australia
Generic and Biosimilar Medicines Association (GBMA)
Medicinal Cannabis Industry Association (MCIA)
Medicines Australia (MA)
Australian Medicinal Cannabis Association (AMCA)

Current revisions of PE009

Annex 1 – Sterile Medicines

- Adopted by PIC/S in PE009-17 (Aug 2023)
- Add ICH Q9, Q10 principles
- Address advances in technology
- Provide clear interpretation of GMP expectations

Chapter 4 - Documentation

- Address modern methods for record keeping
- Incorporate Data Integrity and Data Management

Annex 11 – Computerised Systems

- Incorporate Data Integrity and Data Management
- Add ICH Q9, Q10 principles
- Include evaluation and management of services, e.g. cloud services
- Retention of knowledge
- Classification guidance for critical systems and critical data
- System security – physical and electronic

Annex 4 - Veterinary medicinal products other than immunologicals

- Current version written 1992
- Updates required to incorporate contemporary GMP
- Align with Ch 3/5 for x-contamination
- I(V)MP
- Implement ICH Q8, 9, 10 11 and VICH guidance
- Extend concepts to include new areas of technology, new products, new processing methods
- Address ambiguity
- Tailored to VET (batch sizes, large volumes)

Annex 5 - Manufacture of immunological veterinary medicinal products

- As per Annex 4
- Address ATMP, bloods, cell therapy, gene therapy, animal extracted products, allergen products and biotech products

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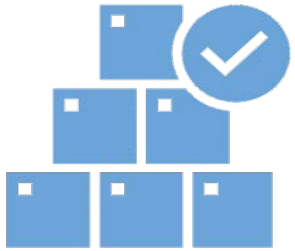
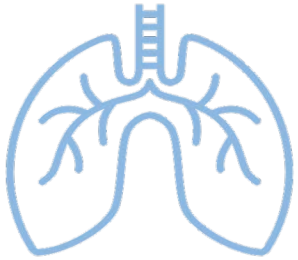
Future revisions of PE009



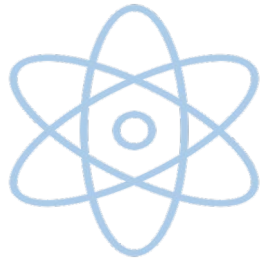
Chapter 1
PQS

Annex 3
Radiopharmaceuticals



Annex 6
Medicinal Gases

Annex 15
Qualification &
Validation



Annex 12
Use of ionising
radiation

Summary

- Reviews of PE009-17 commenced
- TGA continues to work with industry on adoption of future changes
- Multiple changes anticipated in future
- Get involved!
  - PIC/S – EC Feedback
  - TGA/TIWGG Feedback

Questions?

Scan this QR code with your device to submit a question

GMP FORUM 2024

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration