SUMMARY CHANGES TO ANNEX 1 EU GMP VOL IV

by John Johnson

1 SCOPE

> Provides links to other related parts of GMP e.g. 2003/94 Article 5, 2001/83 Article 23, Chapter 3, Chapter 5.10

2 PRINCIPLES

> Reinforces existing GMP requirements

3 GENERAL

> Eliminates contradictions

4 PQS

> Emphasizes need for quality risk management, root cause analysis and impact assessment

5 PERSONNEL

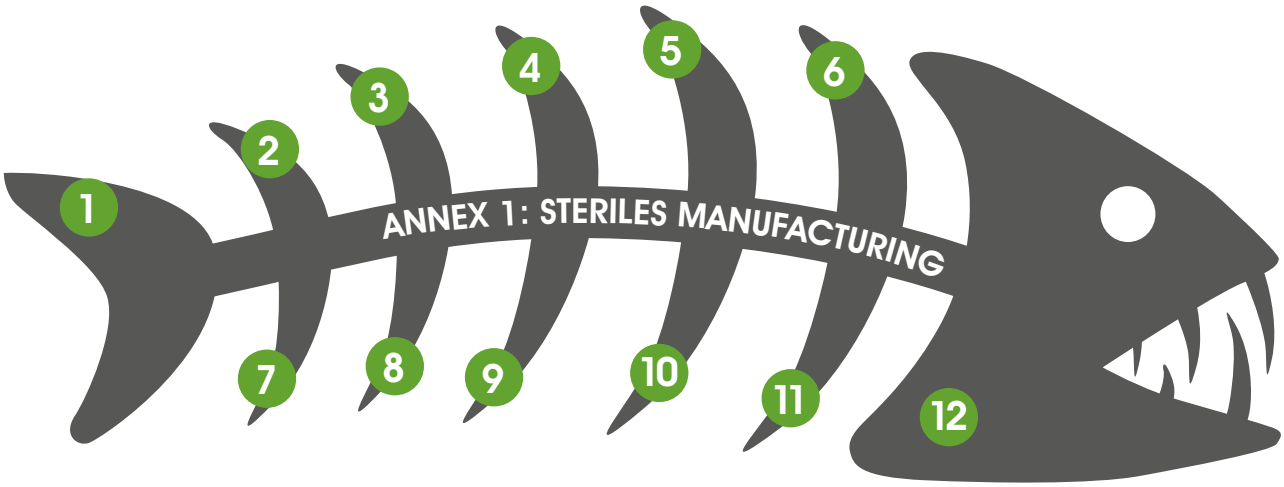
> Emphasizes training and education and importance of staff behaviors

> Need for goggles in critical zone

6 PREMISES

> Implementation of ISO 14644

> Clarifies need for monitoring of 5 micron particles in cleanrooms, reinforces the importance of trending



7 EQUIPMENT

> Emphasizes need to separate operators from process using RABs and isolators

8 UTILITIES

> Requirements for compressed air, prevention and removal of biofilms in water systems

> Generation of WFI will align with Ph. Eur. i.e. use of reverse osmosis will be permitted

9 PRODUCTION

> Clarification on requirements on pre/post use filter integrity testing

> Special reference to "blow fill seal," "small batch production" e.g. ATMPs

> Lots of discussion on expectations for 100% or sampled tests container closure integrity

10 MONITORING

> Reference to rapid ID methods

> Process simulation trials

> Clarification of expectations regarding viable and non-viable monitoring (e.g. frequency)

> Risk assessment must be used to develop environmental monitoring regime

11 QC

> No significant changes expected

12 GLOSSARY

> Useful glossary of technical terms to be included

Origin of the Changes	Andy Hopkins (MHRA) along with a Joint EMA PIC/S Working Party
Timeline	> Draft concept paper issued by MHRA to EMA Inspection Working Group (IWG): September 2014 > Full draft issued to EMA IWG: Second quarter, 2016 > Concept paper to be published: January or February 2017
Reason for Change	> Alignment of Annex 1 with current industry expectations and technologies > Clarification of some key requirements > First major review since inception in 1996 > Alignment to ICH Q9 & Q10 > New/emerging sterile manufacturing entities require additional detail
Key Quote	*"No adverse impact on industry with respect to either resources or costs is foreseen."* – Andy Hopkins > NSF would add that this of course depends on the level of CGMP compliance in place at your facility at present. When regulations change, how do you respond and how do staff behaviors affect your ability to embed the changes?

ABOUT THE AUTHOR

John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms, holding senior operational and corporate-level experience in operations and quality assurance and leading multinational companies in many strategic projects.

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Cite as: NSF International. June 2017. Summary changes to Annex 1 EU GMP Vol IV. NSF: York, UK.

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LPH-434-0617