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and qualification (verification) of pharmaceutical water and steam systems. The guide focuses on items which directly affect quality attributes of water or steam during production, storage, and distribution.

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Steam Systems (Second Edition) with particular emphasis placed upon the new chapters for microbial control and laboratory water as well as key design philosophies. The course will include discussion of the upcoming European Pharmacopoeia regulatory change allowing alternative WFI production methods in addition to distillation.

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130 Water is the most commonly used excipient in medicinal products: the minimum quality of water 131 selected depends on the intended use of the product, according to a risk based approach to be applied 132 as part of an overall control strategy. Guideline on the quality of water for pharmaceutical use

EMA/CHMP/CVMP/QWP/496873/2018 Page 6/10

Guideline on water for pharmaceutical use

2.4 Water sources and treated water should be monitored regularly for chemical, microbiological and , as appropriate,

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endotoxin contamination. The performance of water purification, storage and distribution systems should also be monitored. Records of the monitoring results, trend analysis; and any actions taken should be maintained.

WHO GOOD MANUFACTURING PRACTICES: WATER FOR PHARMACEUTICAL USE

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3.2.1 Drinking-water should be supplied under continuous positive pressure in a plumbing system free of any defects that could lead to contamination of any product. 3.2.2

Drinking-water is unmodified except for limited treatment of the water derived from a natural or stored source. Examples of natural sources include

Annex 2 WHO good manufacturing practices: water for ...

The ISPE Baseline® Guide: Commissioning and Qualification (Second Edition) provides practical guidance on the implementation of a science and risk-based approach for the Commissioning and Qualification (C&Q) of

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pharmaceutical manufacturing facilities, systems, utilities, and equipment to demonstrate that they are suitable for the intended purpose.

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About ISPE The Institute of Swimming Pool Engineers was set up in 1978 to establish an organisation for the individual swimming pool engineer (no corporate membership) to: foster a professional approach to the design, installation and maintenance of swimming pools, enclosures and all ancillary equipment;

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