Pharmaceutical Water Systems: Temperatures of Operation and Maintaining Control

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Introduction

Pharmaceutical water systems can be divided, amongst other criteria, into hot and cold systems. Many purified water systems are cold systems, subject to periodic chemical or ozone sanitization; whereas the water of highest (and thus greatest criticality) - Water-for-Injections (WFI) - tends to be a hot system. WFI is produced by either distillation (Vapor Compression Distillation or Multiple Effect Distillation) (1), or by reverse osmosis. WFI is used for the preparation of parenteral medicines, dialysis and irrigation solutions (2). Large volumes are also consumed by the biotechnology industry for the preparation of cell culture media. The objectives of water purification are three fold:

1. To reduce the levels of the chemical components in the water to prevent interactions with the drug substance, and to prevent toxicity to the patient. Toxicity is possible when large volumes are either infused or used in conjunction with dialysis.
2. To reduce the microbial bioburden to the specified levels and to prevent further proliferation.
3. To remove endotoxins and to prevent their future accumulation.