



GOOD PRACTICE GUIDE:  
**Critical Utilities**  
**GMP Compliance**

*How to Be Compliant and  
Ready to Prove It*

Controlled Process

Sanitization  
and Microbial  
Control

Documented Proof

Regulatory

Inspection Preparation  
and Hosting







GOOD PRACTICE GUIDE:

# Critical Utilities GMP Compliance

*How to Be Compliant and  
Ready to Prove It*

**Disclaimer:**

This Good Practice Guide is intended to provide guidance on achieving and maintaining critical utility systems compliance, and to be an aid to organizations in preparing and hosting regulatory inspections and audits. This Guide is solely created and owned by ISPE. It is not a regulation, standard or regulatory guideline document. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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# Preface

Because of their hidden nature, critical utility systems are vulnerable to noncompliance. With their potential to impact product quality or performance in a significant way, critical utilities consistently receive close scrutiny by regulatory inspectors. This ISPE Good Practice Guide: Critical Utilities GMP Compliance – How to Be Compliant and Ready to Prove It aims to assist pharmaceutical organizations achieve and maintain their critical utility systems in a state of control, and then efficiently demonstrate these systems' GMP compliance to regulatory inspectors and auditors.

It is not the goal of this Good Practice Guide to provide tips on how to pass an inspection; rather the intent is to provide guidance on achieving and maintaining compliance, and to be an aid to organizations when preparing the documents, personnel, and site logistics to help ensure inspections are efficiently conducted, making good use of the limited resources of regulators.

# Acknowledgements

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# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Overview .....	7
1.2	Purpose.....	7
1.3	Scope.....	8
1.4	Key Terms .....	8
<b>2</b>	<b>Critical Utilities Viewed from a Regulatory Perspective.....</b>	<b>11</b>
2.1	Drinking/Potable Water .....	11
2.2	Compendial Water Pretreatment .....	14
2.3	Purified Water .....	14
2.4	Water for Injection.....	15
2.5	Pure Steam.....	15
2.6	Clean Compressed Air.....	16
2.7	Process Gases.....	17
<b>3</b>	<b>Validation Lifecycle and Quality Systems .....</b>	<b>21</b>
3.1	Validation .....	21
3.2	Change Control.....	24
3.3	Risk Management.....	25
3.4	Drawings and Documentation.....	27
3.5	Investigations and Corrective Actions and Preventive Actions .....	32
3.6	Sampling and Testing.....	36
<b>4</b>	<b>Ongoing Operations .....</b>	<b>39</b>
4.1	Data Integrity, Handling, and Automation.....	39
4.2	Sanitization and Microbial Control In Pharmaceutical Water Systems .....	43
4.3	Maintenance .....	47
4.4	Hoses.....	49
4.5	Routine System Reviews .....	50
4.6	Calibration.....	52
4.7	Training .....	54
<b>5</b>	<b>Legacy Water Systems .....</b>	<b>57</b>
5.1	Sources of Legacy Systems .....	57
5.2	Types of Deficiencies and What Can Be Done .....	57
5.3	Regulatory Impact of Legacy Systems .....	60
<b>6</b>	<b>Appendix 1 – Typical Regulatory Citations/Warning Letters .....</b>	<b>61</b>
6.1	Letter 1 – Failure to Validate and Monitor the Water Purification System.....	61
6.2	Letter 2 – Failure to Test Water Used in Drug Product Manufacture .....	62
6.3	Letter 3 – Inadequate Purified Water System Controls.....	62
6.4	Letter 4 – Water System Failures .....	63
6.5	Letter 5 – Inadequate Investigations.....	64
6.6	Letter 6 – Failure to Validate and Monitor the Water Purification System.....	65
6.7	Letter 7 – Failure to Validate Purified Water System .....	66
6.8	Letter 8 – Data Integrity Failures.....	67
6.9	Letter 9 – Lack of or Insufficient Investigation of Water System Failures .....	68

- 7 Appendix 2 – Inspection Hosting Good Practices and Readiness Checklist..... 69**
  - 7.1 Inspection Hosting and Behaviors ..... 69
  - 7.2 Opportunities for Improvement ..... 70
  - 7.3 Inspection Readiness Checklist..... 72
  
- 8 Appendix 3 – Sampling Practice and Planning Supplemental Information ..... 75**
  - 8.1 Testing SOP and Test Materials Preparation ..... 75
  - 8.2 Examples of Good and Poor Water Sampling and Water Use Practices..... 75
  - 8.3 Microbial Discrepancies Caused by Poor Sampling Methods ..... 76
  - 8.4 Sampling Plan..... 77
  
- 9 Appendix 4 – Compendial Water Specifications ..... 79**
  
- 10 Appendix 5 – Microbial Enumeration: Consideration of Nutrient Media, Incubation Temperature, and Incubation Time ..... 85**
  - 10.1 Growth Medium Choice ..... 85
  - 10.2 Incubation Conditions (Temperature and Duration) ..... 86
  
- 11 Appendix 6 – References ..... 87**
  
- 12 Appendix 7 – Glossary ..... 93**
  - 12.1 Acronyms and Abbreviations ..... 93
  - 12.2 Definitions ..... 95