



The ISPE Good Practice Guide

Sampling for
Pharmaceutical Water,
Steam, and Process Gases

Brian Hagopian, CPIP
Chemist and President
Clear Water Consulting, Inc.

ISPE Boston Area Chapter
February, 2017

About Clear Water Consulting

Clear Water Consulting provides these services to the Life Sciences Industry:

- **Optimize the operation and performance of water systems**
- **Expert troubleshooting if something's just not right**
- **Training and Education**
 - Pharmaceutical Water
 - State Certified Industrial Wastewater Trainer
 - On-line training will be available starting later in 2017
- **Documentation to support validation, CAPA's, and OOS investigations**



Connecting

Pharmaceutical

Knowledge

ispe.org | 2

The ISPE Good Practice Guide Sampling for Pharmaceutical Water, Steam, and Process Gases



GOOD PRACTICE GUIDE:
**Sampling for
Pharmaceutical Water,
Steam, and Process Gases**



Why was this Guide needed?

Errors due to sampling are costing the industry millions

Very little regulatory guidance

First of its kind Sampling Guide

Will be an Industry Benchmark

“Identifying the elements of proper sampling and eliminating the underlying reasons for these negative consequences formed the primary driving force behind this ISPE GPG”



Connecting

Pharmaceutical

Knowledge

ispe.org | 3

The ISPE Sampling GPG

Over 15 SME's from around the world

Vetted by over 50 reviewers

Pharma Water User Group Input

Took over 3 years to complete

Acknowledgements

This Good Practice Guide was produced by a dedicated Task Team of Subject Matter Experts (SMEs) led by Brian Haggopian, CPIP (Clear Water Consulting, Inc.). The work was supported by the ISPE Critical Utilities Community of Practice (COP).

The authors and contributors to this Good Practice Guide are listed below, but the following people deserve special recognition for their extensive involvement in developing and vetting the content for this guide: Joseph Manfredi and Teri C. Sok, PhD for the Water Chapter, Brian Pochini, CPIP for the Steam Chapter, and Ruby Ochoa for the Process Gas Chapter.

Chair		
Brian Haggopian, CPIP	Clear Water Consulting, Inc.	USA
Chapter 1: Introduction		
Brian Haggopian, CPIP (Chapter Lead)	Clear Water Consulting, Inc.	USA
Chapter 2: Pharmaceutical Water		
Michael Baumstein	Pfizer, Inc.	USA
Rod Freeman	Beckman Coulter, Inc.	USA
Brian Haggopian, CPIP	Clear Water Consulting, Inc.	USA
Jeppe Kjems	CU Engineering	Denmark
Joseph Manfredi (Chapter Lead)	GMP Systems, Inc.	USA
Aravind Palinvelu	Roche	Singapore
Teri C. Sok, PhD	Soli Pharma Solutions, Inc.	USA
Michael Tomaselli	Filters, Water, and Instrumentation, Inc.	USA
Chapter 3: Pharmaceutical Steam		
Michael Baumstein	Pfizer, Inc.	USA
Andre Gill, PE	Andre Gill Engineering	USA
Brian Haggopian, CPIP	Clear Water Consulting, Inc.	USA
Joseph Manfredi	GMP Systems, Inc.	USA
Brian Pochini, CPIP (Chapter Lead)	Sanofi	USA
Teri C. Sok, PhD	Soli Pharma Solutions, Inc.	USA
Philip Sumner, PE	Pfizer, Inc.	USA
Nancy Tomoney	West-Ward Pharmaceuticals	USA
Anders Widow	Wiphe AB	Sweden
Chapter 4: Process Gases		
Michael Baumstein	Pfizer, Inc.	USA
Brian Haggopian, CPIP	Clear Water Consulting, Inc.	USA
Ruby Ochoa	Trace Analytics, LLC	USA
Aravind Palinvelu	Roche	Singapore
Michael Vestlermark	Novo Nordisk Biopharm	Denmark
Peter Vashon (Chapter Lead)	Independent Consultant	USA
Glossary		
Michelle Gonzalez, PE	Amgen, Inc. (retired)	USA



Connecting

Pharmaceutical

Knowledge

ispe.org | 4

The ISPE Good Practice Guide

Sampling for Pharmaceutical Water, Steam, and Process Gases

Table of Contents

1 Introduction	7
1.1 Background.....	7
1.2 Overview.....	10
1.3 Scope and Purpose.....	10
1.4 Benefits.....	11
1.5 Objectives.....	11
1.6 Key Concepts/Terms.....	11
2 Pharmaceutical Water	13
2.1 Introduction.....	13
2.2 Determining Sampling Locations.....	19
2.3 Developing Sampling Plans.....	24
2.4 Sample Valve Design.....	38
2.5 Sampling Techniques.....	40
2.6 Handling of Samples.....	44
2.7 Parametric (Real Time) Release.....	48
3 Pharmaceutical Steam	51
3.1 Introduction to Pharmaceutical Steam.....	51
3.2 Generation and Distribution of Pharmaceutical Steam.....	51
3.3 Sampling Locations.....	56
3.4 Sampling Plans (Frequency and Duration).....	63
3.5 Sample Valve Design.....	68
3.6 Pure Steam Sampling Techniques.....	68
3.7 Sample Handling.....	76
3.8 Other Factors Influencing Sampling Strategies.....	76
4 Process Gases	81
4.1 Introduction.....	81
4.2 Sampling Locations.....	83
4.3 Sampling Plan (Tests Performed, Frequency and Duration).....	88
4.4 Sample Valve Design.....	91
4.5 Gases Sampling Techniques for Compressed Air and Process.....	91
4.6 Sample Handling.....	94
4.7 System Monitoring.....	94

120 pages of Guidance

Similar chapter format

5 Appendix 1 - Specification Summary for Various Non-Pharmaceutical Water Grades	95
6 Appendix 2 - Examples of Water System Sampling Point Locations	97
7 Appendix 3 - Factors Influencing Pure Steam Generator Performance	101
7.1 Source Water.....	101
7.2 Steam Generator Mist Elimination Capability.....	102
7.3 Non-condensable Gas Removal Capability.....	103
7.4 Blow Down Adjustment.....	103
7.5 Potable Water Chloramine Use.....	103
7.6 Anti-scaling Steam Additives.....	103
7.7 Monitoring Locations and Frequency.....	104
8 Appendix 4 - References	105
9 Appendix 5 - Glossary	107
9.1 Acronyms and Abbreviations.....	107
9.2 Definitions.....	109



Connecting

Pharmaceutical

Knowledge

ispe.org | 5