ISPE

Good Practice Guide

# Process Gases

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**Disclaimer:**
This Guide is meant to assist pharmaceutical companies in determining accepted good processes and procedures for gas systems used to support production. The 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

The purpose of the ISPE Good Practice Guide: Process Gases is to document accepted good processes and procedures within pharmaceutical manufacturing applications. The Guide promotes science- and risk-based methods for the design, construction, commissioning, and qualification processes for gas systems used to support production.

This Guide considers those gases that come into direct contact with the biopharmaceutical and pharmaceutical manufacturing process streams; these include:

- nitrogen
- oxygen
- argon
- carbon dioxide
- compressed air

This Guide aims to define current good practices in this area, providing information to allow organizations to benchmark their practices and improve on them. The Guide also considers some of the issues relating to sustainability and economics.

The intended audience for this Guide is global, with particular focus on US (FDA) and European (EMA) regulated facilities.

The information provided in this Guide reflects the cumulative knowledge and experiences of the authors, editors, and reviewers. There is no single approach to satisfy every situation; but this Guide attempts to provide the background to assist readers to make an educated choice.

# Acknowledgements

This Guide was developed by a team led by Chad Larrabee of Ingersoll Rand Industrial Technologies and Nicholas Haycocks of Amgen.

## Section Writers and Reviewers

The ISPE Good Practice Guide: Process Gases has been sponsored by engineering executives from owner organizations, consulting firms, and ISPE senior management.

This Guide was produced by a dedicated team of subject matter experts from across the industry. The leaders of this Guide would like to recognize the following participants who took lead roles in the authoring of this document. (Organization affiliations are as of the final draft of the Guide.)

| | | |
|---|---|---|
| Katrin Åkerlindh | Linde Gas | Sweden |
| Tracey Coffey | Commissioning Agents, Inc. | USA |
| Joseph DePaul | Skye Technical Services | USA |
| Roger Emmett | Praxair Distribution Inc. | Canada |
| Michelle Gonzales | Amgen (retired) | USA |
| Nicholas Haycocks | Amgen | USA |
| Wade Johnston | CIBA VISION Corp. (A Novartis Company) | USA |
| Tom Larkin | Integrated Process Technologies | USA |
| Chad Larrabee | Ingersoll Rand Industrial Technologies | USA |
| Jerold Martin | Pall Corp., Life Sciences div. | USA |
| Bonnie Smelser | Progenics Pharmaceuticals Inc. | USA |
| Frank van der Steen | SynCo Bio Partners B.V. | The Netherlands |
| Peter Vishton, P.E. | IPS Contract Engineer, GMP Utility Systems | USA |
| Ian Nicholson | IDT Australia | Australia |

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Many other individuals reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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**ISPE Headquarters**
600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA
Tel: +1-813-960-2105, Fax: +1-813-264-2816

**ISPE Asia Pacific Office**
73 Bukit Timah Road, #04-01 Rex House, Singapore 229832
Tel: +65-6496-5502, Fax: +65-6336-6449

**ISPE China Office**
Suite 2302, Wise Logic International Center
No. 66 North Shan Xi Road, Shanghai, China 200041
Tel +86-21-5116-0265, Fax +86-21-5116-0260

**ISPE European Office**
Avenue de Tervueren, 300, B-1150 Brussels, Belgium
Tel: +32-2-743-4422, Fax: +32-2-743-1550

**www.ISPE.org**

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# 1 Introduction

## 1.1 Purpose

The purpose of the ISPE Good Practice Guide: Process Gases is to document accepted good processes and procedures within pharmaceutical manufacturing applications. The Guide promotes science- and risk-based methods for the design, construction, commissioning, and qualification processes for gas systems used to support production. The Guide is intended to align with ICH Q9 and ASTM E2500-07 (References 3 and 23, Appendix 8).

## 1.2 Scope

This Guide considers those gases that come into direct contact with the biopharmaceutical and pharmaceutical manufacturing process streams; these include:

- nitrogen
- oxygen
- argon
- carbon dioxide
- compressed air

Medicinal or medical gases, breathing air, and steam are outside the scope of this Guide.

Process streams include bodily contact surfaces of invasive medical devices and fluid paths of medical devices that are used for intravenous solution, blood, or other critical applications to administer life saving or sustaining fluids.

This Guide focuses on defining cost effective engineering approaches and practices used to deliver process gas systems for a manufacturing facility in a timely manner that will meet its intended purpose. Specifically, the Guide addresses the process of designing, constructing, commissioning, and qualifying a process gas system regulated by the FDA or other regulatory authorities, e.g., the EMA. The Guide also addresses international guidelines and regulations.

The Guide is neither a standard nor a GMP. It is not intended to replace governing laws, codes, standards, or regulations that apply to facilities of this type. These are mentioned only for completeness and where their impact affects facility, equipment, and utility design relative to cGMPs. The use of this document for new or existing facilities, equipment, or utilities is at the discretion of the owner or user.

This Guide is not intended to address any aspect of process/product validation. This is a subject that has been well defined by the FDA and other authorities, and for which substantial guidance documentation exists.

## 1.3 Benefits

This Guide describes the fundamentals of process gas systems used within the GMP workplace environment and provides:

- guidance on accepted industry practices related to gas systems
- the life science engineering community with a common language and understanding of gas systems