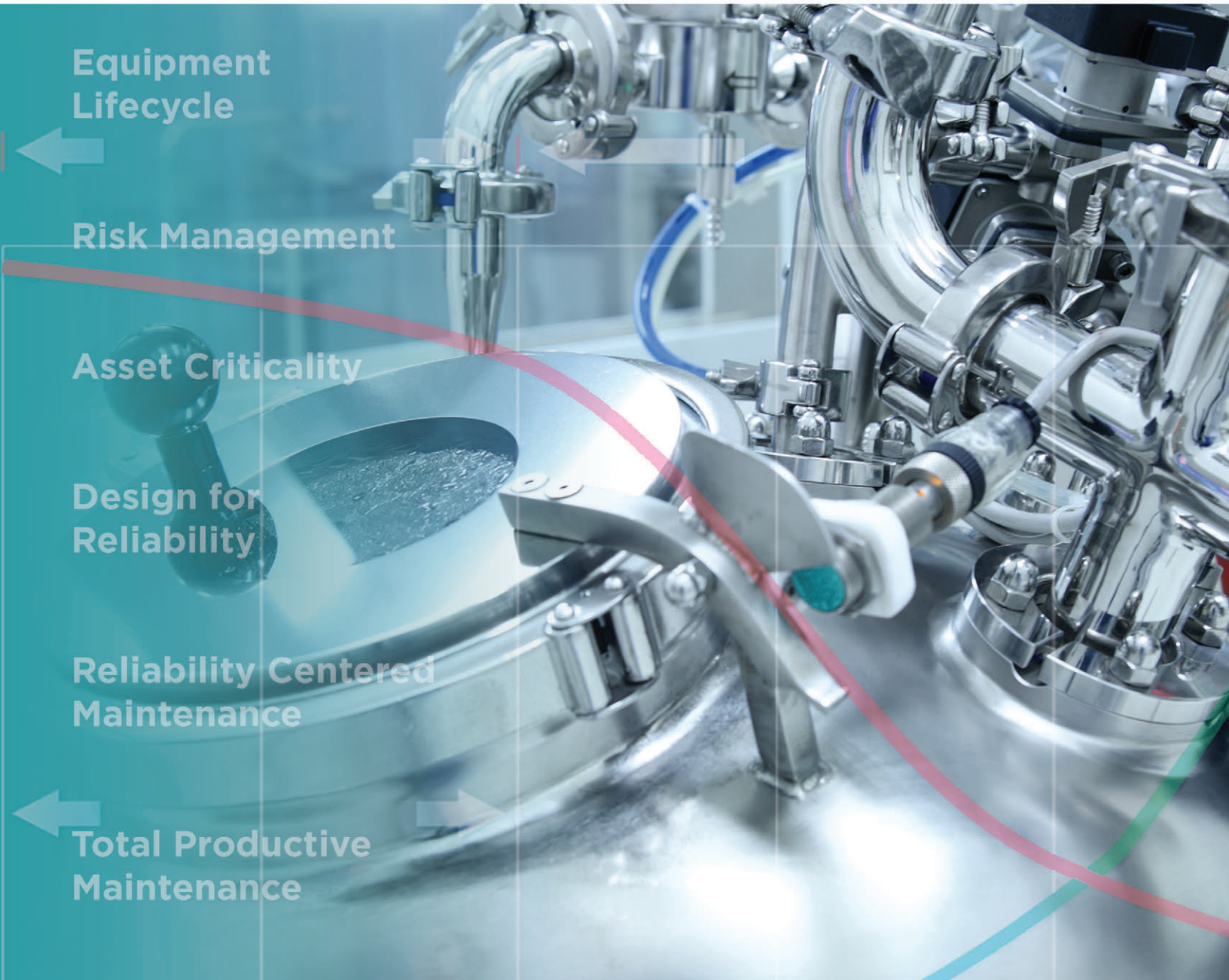
ISPE®

GOOD PRACTICE GUIDE:

Equipment Reliability



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ISBN 978-1-946964-37-3

Preface

The current climate within the industry continues to rely upon innovation for success. The appeal for innovation expands beyond new products and is accompanied by increased pressure to provide for affordable healthcare. Whether for new or legacy products, a reliable supply chain and effective cost management are critical for satisfying customer needs.

The application of asset management principles can leverage equipment towards competitive advantage. As innovation extends to and transforms the supply chain, equipment lifecycle costs and availability become ever more relevant to maintaining a competitive advantage. Reliable equipment improves the likelihood of achieving reliable operations and thus improves the supply of critical therapies to patients worldwide.

This *ISPE Good Practice Guide: Equipment Reliability* intends to provide guidance on the application of equipment reliability concepts to systematically and proactively improve equipment reliability at all stages of the equipment lifecycle. This Guide is not intended to provide the basic body of knowledge for equipment reliability or reliability engineering. This Guide offers best practices with respect to equipment reliability, addresses specific opportunities for the pharmaceutical industry beyond the general reliability of equipment, and can serve as the basis for an effective reliability program.

Acknowledgements

The Guide was produced by a Task Team led by Michael Berkey (Merck & Co., Inc., Kenilworth, NJ, USA).

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Special Thanks

The Team would also like to thank ISPE for technical writing and editing support by Nina Wang and Jeanne Perez (ISPE Guidance Documents Technical Writers/Editors) and production support by Lynda Goldbach (ISPE Guidance Documents Manager).

The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

Company affiliations are as of the final draft of the Guide.

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1 Introduction

1.1 Background

Equipment reliability is concerned with the risk of failures in equipment and processes, providing focus on equipment availability, fitness for purpose, and cost. The strategy and tactics of reliability contribute to realizing the value of equipment throughout its useful life and mission. Reliability and maintenance strategies are developed to reduce the risk and impacts of equipment failure. From a management perspective, reliability can be viewed as a set of techniques applied through an attitude of anticipating unreliability (instability) and an appreciation for the proactive elimination of issues. The techniques presented in this Good Practice Guide concentrate on equipment reliability, whether directly or indirectly related to product supply.

1.2 Purpose and Value

This Guide aims to provide guidance on the application of equipment reliability concepts in the context of the pharmaceutical, medical device, biologics, blood, and/or advanced therapy industries. These concepts are applicable to facilities, utilities, systems, and equipment assets. The Guide intends to:

- Provide recommendations and best practices for organizations to develop and apply solutions for asset and maintenance strategies to optimize equipment performance and minimize the total cost of ownership
- Allow for flexibility in implementing equipment reliability principles with respect to organizational size, resources, asset age, and maturity
- Apply a lifecycle approach to equipment assets
- Be complementary to other ISPE Guides for related aspects of asset management and maintenance [1, 2]

The value offered by this Guide includes:

- Presenting techniques to systematically and proactively improve equipment reliability at all stages of the equipment lifecycle (design, installation, commissioning/qualification, operations and maintenance, and decommissioning)
- Raising awareness of the contribution of assets (conditions) to the management of business continuity risk
- Influencing the pharmaceutical industry to move toward more reliable assets by focusing on the systematic reduction of equipment performance variation and its operating impact, through improved equipment design and management
- Improving manufacturing processes, support processes, and product quality by ensuring continued fitness for purpose and availability of equipment
- Addressing the events and consequences of equipment failures, by providing guidance on effective tools and strategies to be applied to an organization’s systems
- Focusing on equipment reliability as a means of reducing and managing risk with respect to business operations, supply, product quality, compliance, and reputation