



Points to Consider for Aging Facilities

www.pda.org/bookstore

To order this document, please visit go.pda.org/PTC-Aging

PDA Points to Consider for Aging Facilities Team

Authors and Contributors

Ghada Haddad, Merck & Co./Merck, Sharp & Dohme, Co-Chair

Maik Jornitz, G-CON Manufacturing Inc., Co-Chair

Glenn Wright, Eli Lilly and Company, Co-Chair

James Butler, Cimetrics

Jette Christensen, Ph.D., Novo Nordisk

Phil Desantis, DeSantis Consulting Associates

Robert Dream, Ph.D., HDR CO., LLC

John Lewis, DPS Consulting, Inc.

Anette Marcussen, Novo Nordisk

Morten Munk, NNE Pharmaplan

Shelley Preslar, Azzur Group

Susan Schniepp, Regulatory Compliance Associates Inc.

Chris Smalley, Ph.D., ValSource

Matthew Taylor, Eli Lilly and Company

George Wiker, AES Clean Technology

Points to Consider for Aging Facilities

ISBN: 978-0-939459-97-1

© 2017 Parenteral Drug Association, Inc.

All rights reserved.



Table of Contents

| | |
|--|----|
| 1. INTRODUCTION | 1 |
| 2. RECOGNIZING A FACILITY IS AGING | 2 |
| 3. IMPEDIMENTS TO MODERNIZATION | 4 |
| 4. BUSINESS CASE FOR MODERNIZATION..... | 6 |
| 5. STRATEGIES FOR MODERNIZATION | 8 |
| 6. IMPACT OF CHANGING STANDARDS | 19 |
| 7. SLOWING THE AGING PROCESS..... | 20 |
| 8. REGULATORY | 22 |
| 9. REFERENCES..... | 24 |

1. Introduction

Aging facilities contribute to a variety of challenges in pharmaceutical manufacturing, including drug shortages and product recalls. No two facilities are identical in their design, processes, increased manufacturing costs, employee safety issues, or extent to which they have aged. With such variation, specific plans regarding modernization must be facility-specific. There are, however, general concepts and approaches that can be considered on how to identify and modernize aging facilities.

One common challenge to modernization for many companies is having the necessity for additional financial and operational resources. The cost of modernization can be very high, and even innovator firms with major markets for “blockbuster” products are faced with decisions on how and when to perform modernization activities. Certainly, for facilities operating with low cost products those additional financial and operational resource needs are even more challenging.

In an existing, and therefore aging, facility, the theoretical methods presented in these risk management tools can be supported with actual plant data. The strength of risk management in determining what to do with an aging facility is that it not only identifies risks, but quantifies or categorizes them in a manner that allows serious consideration of a path forward. When risks are studied, the threat to company goals becomes real rather than hypothetical. Risk management can identify potential problems before it becomes too late to address them. In every case, however, the need to properly plan and implement modernization actions to ensure a continuing robust drug product supplies, but also return on investment, is critical. Without modernizing aging facilities, the ability to continue supplying quality product will eventually be affected, generating drug shortages and dissatisfaction among key stakeholders, including regulatory bodies.

A team of industry experts developed this document, based on responses to a PDA workshop held in March 2015 and a survey of PDA members conducted in late 2015. The questions and answers below reflect the general thoughts and suggestions of the pharmaceutical manufacturing industry on how to identify and modernize aging facilities.