

# Combination Products cGMP Compliance

## Table of Contents

### Introduction

<b>Developing a Compliance Strategy .....</b>	<b>5</b>
Three Categories of Combination Products .....	5
Deciding When to Use the Streamlined Approach .....	7
When Certain Requirements Don't Apply.....	9
Developing a Regulatory Strategy.....	10
Case Study: Drug PMOA .....	12
Case Study: Device PMOA.....	14
Implementation Challenges .....	16
<b>Impact of Business Processes on the Compliance Strategy.....</b>	<b>20</b>
Product Development.....	20
Strategic Planning.....	21
Sales and Ops Planning .....	22
<b>Appendices.....</b>	<b>24</b>
A. 21 CFR Part 4	
B. Current Good Manufacturing Practice Requirements for Combination Products (Final Rule)	
C. Current Good Manufacturing Practice Requirements for Combination Products (FDA draft guidance)	
D. 21 CFR Part 210	
E. 21 CFR Part 211	
F. 21 CFR Part 820	
G. 21 CFR Part 600	