ISO/TR 12417-2:2022-07 (E)

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 2: Local regulatory information

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Information on device- and drug-related aspects -- Applicable documents for local guidance 4
4.1 General 4
4.2 Australia 4
4.2.1 General 4
4.2.2 Australia: Managing changes 5
4.2.3 Australia: Clinical evaluation requirements 5
4.2.4 Australia: Audit requirements 5
4.3 Brazil 5
4.3.1 Brazil: Managing changes 5
4.3.2 Brazil: Clinical evaluation requirements 6
4.3.3 Brazil: Audit requirements 6
4.4 Canada 6
4.4.1 Canada: Managing changes 6
4.4.2 Canada: Clinical evaluation requirements 6
4.4.3 Canada: Audit requirements 6
4.5 European Union (EU) 6
4.5.1 EU: Managing changes 6
4.5.2 EU: Material inclusion and labelling requirements 7
4.5.3 EU: Clinical evaluation requirements 7
4.5.4 EU: Audit requirements 7
4.6 India 7
4.6.1 India: Managing changes 7
4.6.2 India: Clinical evaluation requirements 8
4.6.3 India: Audit requirements 8
4.7 Japan 8
4.7.1 Japan: Managing changes 8
4.7.2 Japan: Clinical evaluation requirements 8
4.7.3 Japan: Audit requirements 8
4.8 People's Republic of China (PRC) 8
4.8.1 PRC: Managing changes 8
4.8.2 PRC: Clinical evaluation requirements 9
4.8.3 PRC: Audit requirements 10
4.9 Russia 10
4.9.1 Russia: Managing changes 10
4.9.2 Russia: Clinical evaluation requirements 10
4.9.3 Russia: Audit requirements 10
4.10 United States of America (USA) 10
4.10.1 USA: Managing changes 10
4.10.2 USA: Clinical evaluation requirements 11
4.10.3 USA: Audit requirements 11

5 Managing changes that can impact the DCP 12
5.1 General 12
5.2 Change evaluation 12
5.2.1 Identify changes 12
5.2.2 Risk evaluation 13
5.2.3 Guidance for change evaluation 13
5.2.4 Pre-market 14
5.3 Interactions with region-specific regulatory authorities -- Post-commercialization 14

Bibliography 22