

Accepted Manuscript

Quality aspects for medical devices, quality system and certification process

Fabio Geremia

PII: S0026-265X(17)30352-1
DOI: doi: [10.1016/j.microc.2017.04.018](https://doi.org/10.1016/j.microc.2017.04.018)
Reference: MICROC 2795
To appear in: *Microchemical Journal*
Received date: 15 September 2016
Revised date: 3 April 2017
Accepted date: 9 April 2017



Please cite this article as: Fabio Geremia , Quality aspects for medical devices, quality system and certification process. The address for the corresponding author was captured as affiliation for all authors. Please check if appropriate. Microc(2016), doi: [10.1016/j.microc.2017.04.018](https://doi.org/10.1016/j.microc.2017.04.018)

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Quality Aspects for Medical Devices, Quality System and Certification Process

Fabio Geremia (CTP Tecnologie di Processo SpA, Milan, Italy)

1. Introduction

Medical devices are nowadays every time more and more important in the healthcare industry and the related processes for worldwide regulation and certification are a topic of great interest and actuality.

As represented in Picture 1 here below, Medical Devices world includes an incredibly wide range of products, this leads to the complexity of the regulatory and certification process and to the fact that all possible categories of products and stakeholders in the healthcare industry must be taken into consideration.

Picture 1



With regards to the importance of Medical Devices field in healthcare industry, a recent article (CountryFocus: Healthcare, Regulatory and Reimbursement Landscape – Italy) estimates that the pharmaceutical market in Italy in the next five years could decrease from 22 billions to 18 billions of USD (3.3% negative trend), while the medical device market in Italy could grow from 13.2 billions to 16.2 billions of USD (4.2% positive trend).

Download English Version:

<https://daneshyari.com/en/article/5138985>

Download Persian Version:

<https://daneshyari.com/article/5138985>

[Daneshyari.com](https://daneshyari.com)