

# 3<sup>rd</sup> International Summit on **GMP, GCP & Quality Control**

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### **Practical experience: Integration of different GMP and ISO in the same facilities**

Laboratoires Quinton manufactures different kinds of products with seawater. Depending on the usage, the product can be:

- Oral use: Dietary supplement
- Nasal use: Hygiene product or medical device
- Skin use: Cosmetic or medical device
- Other use: Medicine

Nowadays, the quality assurance of the product is essential to prevent risks to consumers, therefore, applying a GMP system during the process minimizes the risks and increases the quality of the product.

#### **In our Laboratory, we have implemented the following standards:**

- ISO 9001:2008 (General)
- ISO 14001:2004 (Environmental)
- OHSAS 18001:2007 (Occupational risk prevention)
- ISO 13485:2003 (Medical devices)
- ISO 22716:2007 (Cosmetics)
- GMP dietary supplement (FDA, Title 21 of CFR)

Following one of the principles of the GMP “What is not written is not fact”, the principal tool with which we work is a good documentation system. This must be easy to use, easy to know, checked, dynamic and easy to adapt. Also it should encompass every activity that we do during the manufacture and distribution of the product.

We have followed the index of GMP for medicines, and we have developed every SOP and records trying at all times not to duplicate information and have one SOP valid in an ISO 9001 audit and also valid in an inspection of the Spanish Medicines and Medical Devices Agency.

Some examples are: Internal audits, non conformities, batch traceability, supplier evaluation, purchases, training, document development...

Thereby, we have a system adapted to the future and ready for new challenges.

### **Biography**

Maria Pellin Amoros completed her Pharmacy degree in 2008 at the Miguel Hernandez University and in 2012/2013 did a Bioengineering Masters. In 2009 she started to work in Laboratoires Quinton International S.L as Quality Technician and in 2010 was designated Quality Control and Environmental Manager. The Laboratory obtained the ISO 14001, ISO 22716 and the GMP of dietary supplement and has licenses to manufacture food supplements, cosmetics and, in the future, medical devices. In 2011, Maria started as a Lecturer in the Miguel Hernandez University in the Pharmacy degree given to the students Law and Ethics (4<sup>o</sup> course) and Pharmaceutical Management (5<sup>o</sup> course) in 2013 she started her PhD

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