Maria Pellin Amoros, J Dev Drugs 2014, 3:3
http://dx.doi.org/10.4172/2329-6631.S1.006

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia Convention Centre, Spain

GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality

Maria Pellin Amoros
Laboratoires Quinton International S.L., Spain

Laboratoires Quinton manufactures seawater ampoules as a dietary supplement in two different concentrations, 0.9% and 3.3% of salinity. We follow the protocol of Rene Quinton. He was a biologist who created the laboratory in France in 1897. The protocol follows three important principles: Noadherence of preservatives, keeping the temperature of the product below 40ºC-45ºC and glass packaging. To maintain product safety, excellent quality and taking into account these three values it is necessary to manufacture our product following the GMP.

FDA has a special GMP for dietary supplements and we have implemented this in our facilities and SGS has audited our implementation.

Our process begins by collecting the seawater from specific places. This water is transported in refrigerated trucks under 3-8ºC. The control of this temperature is very important to avoid the growth of microorganisms. When the water arrives at the laboratory we sample all the containers and we do a specific assay to determinate the quality of the water. We store the water in a refrigerated room under 3-8ºC.

To follow the protocol of Rene Quinton, we apply to the water a double micro filtration with filters of 0.22 microns to eliminate the entire bacterial load before packaging in the glass ampoules. This part of the process is performed in a clean room under air quality ISO5.

The difficulties that we encountered when implementing the GMP were: selection and evaluation of suppliers, personnel training, maintenance and documentation. The most important sentence which defines the GMP is "What is not written is not fact" and this is necessary to all who knows the organization, because in GMP everyone is important and everyone should be involved.

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 (4º course) and Pharmaceutical Management (5º course) in 2013 she started her PhD

maria.pellin@quinton.es