

**Classification:** Confidential

## STATE OF THE ART

Solutex has developed and implemented a Quality and Food Safety Management System, based in 22000:2005 and 9001:2008 ISO standards.

Also Good Manufacturing Practices according ICH-Q7A are in place for Active Pharmaceutical Ingredients and their intermediates and 21CFR part 111 for Dietary Supplement's Ingredients.

On 18<sup>th</sup> and 19<sup>th</sup> September of 2014, an inspection by FDA was conducted under CPGM 7303.803 to cover CPGM7321.008 Dietary Supplements, however we are a dietary ingredient manufacturer. As a result, a FDA 483, Inspectional Observations was not issued

Mallén, June 12, 2017



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