President’s Corner
By: Lara Soltis, ITW Texwipes

Auditing API Facilities
By: Frank Settineri, Veracorp LLC
The current guideline for API facilities is Q7A1 which lists seventeen (17) areas to audit. How do you find the time to observe, review, interview and dig deep into a company’s operations?

Unusual Autoclave Temperature Distribution Results
By: Jim Agalloco, Agalloco & Associates
One of the commonly required tests performed in conjunction with the operational qualification of a steam sterilizer is the empty chamber temperature distribution test. In this test, thermocouples are positioned throughout the sterilizer, and the temperature range across the sterilizer measured. (An acceptable distribution range might be anywhere from ±0.5 to ±2.0 C based upon the age and use of the sterilizer).

Global Compendium
By: Luciano Virgili
In the pursuit of a global compendium for medicinal products. A naïve ideal or an ideal pharmacopoeia?

Featured Articles In This Issue:
- Auditing API Facilities
- Unusual Autoclave Temperature Distribution Results
- Global Compendium

Area of Interests:
Click on the link below for details.
- Calendar of Events
- Photo Gallery
- Job Opportunities

Helpful Links
- The Food and Drug Administration www.fda.gov
- The U. S. Pharmacopeia www.usp.org
- International Conference on Harmonization www.ich.org
- International Organization for Standardization www.iso.org

Welcome New Members!
Name, Company
Name, Company

Newsletter Staffs
Newsletter Chair
Robert Johnson

Newsletter Administrator/Coordinator
Mary Huynh

Distribution
Mary Manco

Contact us with any questions or comments on this issue. click here