

## Quality Control/Quality Assurance



### Commitment to Quality



*"Lives depend on a job well done."* For PCCA, it's not just a saying, but the way we approach Quality. While our members have access to over 4,560 active and non-active chemicals – more than any other compounding pharmacy supplier – the competitive advantage we bring our members is the industry's most comprehensive quality control and assurance program we bring to those chemicals every day.

Here is how we differ from the competition:

#### Every Lot - Not Just the Initial Lot - Is Tested

- We do not solely rely upon the USP or manufacturer's label to ensure the quality of the chemicals received.
- Every lot received is tested using Fourier Transform Infrared Spectroscopy, ultraviolet-visible analysis, melting point, specific gravity, solubility and chemical identifications.
- Additional testing of APIs is done using actual formulations.

#### 14 Checks and Analyses Are Performed on Each Chemical Lot As It Comes In and Is Repacked

- Nine qualitative and quantitative analyses are performed on every incoming chemical lot before it is released for repacking or sale.
- Each lot is tested against the certificate of analysis (C of A), including: USP, EP, NF, FCC, ACS and PCCA standards.
- After initial testing, all results are reviewed for accuracy by a second QC analyst.
- Chemicals are tested only by degreed Chemical Analysts.

#### Five Validation Checks Are Made During Each Repack Order, Including:

- Written and audited Label Control procedures.
- Production audits performed by the QA department followed by a second identity test performed by QC department on repacked chemicals.

**PCCA Rejects About 180 Chemical Lots Per Year, or Just Over Three Lots Received Per Work Week**

- PCCA is fully registered by the FDA, DEA and State of Texas as a manufacturer and follows current Good Manufacturing Practices (cGMP).
- Only FDA-registered and GMP-certified manufacturers are used for the purchase of active pharmaceutical ingredients (APIs).

**Dr. Pamela Smith and Dr. John Monaco discuss the quality of PCCA bases and chemicals.**



## Quality Doesn't Stop With High-Quality Chemicals

Compounding pharmacies complete the quality circle by testing their compounded preparations through an independent lab such as Eagle Analytical Services. Eagle Analytical helps pharmacists close the quality circle by testing preparations on an ongoing basis including sterility testing, bacterial endotoxins, microbial detection, beyond-use date (BUD) determination and active-ingredient potency. They not only test the preparation, they test the processes behind the preparation, giving pharmacies top-to-bottom confidence in their products.

- Dedicated service, expertise, and state-of-the-art equipment.
- Timely online access to test results.
- Eagle Analytical coordinates with PCCA consultants to troubleshoot your problem compounds.

Find out more about Eagle Analytical's quality testing by visiting [www.eagleanalytical.com](http://www.eagleanalytical.com).

**Watch the video below, in which Bill Zolner, PhD, Chief Scientific Officer of Eagle Analytical Services, describes process verification.**

[Click here to download more information from Dr. Zolner about quality.](#)

[Click here for more information about Eagle services.](#)



#### Contact PCCA

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#### We Want to Hear From You

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Anti-Spam: Number of "C"s in PCCA: