



Roger James,  
General Manager  
CAMAG Scientific, Inc. CSI  
Wilmington, NC  
tlc@camagusa.com

Dear reader,

As a branch of the international CAMAG-Laboratory network, the Lab at CSI is dedicated to the highest quality of services for their customers. For more than a decade we have performed HPTLC analyses in full compliance with cGMP for the pharmaceutical industry.

Quality control of botanicals in the context of the new cGMP rules is not rocket science! We can do it and more importantly, you can do it as well. Within our network we are concentrating on the development and validation of methods for identification of botanicals from traditional Western Ayurvedic to Traditional Chinese Medicines. We work closely with AHP, USP, AOAC, and hold membership in AHPA and UNPA.

We can be a good partner and provide strong support when it comes to setting up a small lab, developing quality control routines for production, adopting those compendial monographs to your needs, interpreting analytical data, or developing ID methods for all your botanicals and special products.

The Lab at CSI also offers training programs for HPTLC, helping you master the challenges of these new regulations. Through our affiliation with network partners in Europe, China, and India we think we are an integral part of the botanicals industry and have a vested interest in the quality of the products that come from that industry, not just in the USA but worldwide. With that in mind we hope you will take advantage of our know-how, our broad experience and close associations in the industry.

Call 1-877-HPTLC-4-U

## News & Events

### New brochures:

- HPTLC technology for the analysis of botanical materials and products

### Events:

- Workshop »Wirkungsbezogene Analytik mit HPTLC«, 22 August 2007, Muttenz
- EURO FOOD Chem XIV, 29–31 August 2007, Paris/France
- 55th Annual Meeting and International Congress of the Society for Medicinal Plant Research, 2–6 September 2007, Graz/Austria
- Curso de Cromatografía HPTLC Moderna, 05–07 Sept. 2007, Universidad de Concepción, Chile

# CAMAG

*Flash*

July 2007

## cGMP for the botanical industry – Mandated for the USA but expected to impact worldwide!



**Sure  
you know what  
you just bought?**

In June the US FDA published “Current Good Manufacturing Practice in Manufacturing, Packing, Labelling, or Holding Operations for Dietary Supplements” (cGMP). For the botanical industry this is a fundamental step toward consistently ensuring the quality and safety of its product. Depending on their size, manufacturers will have between one and three years to establish compliance. It is expected that this regulation will also have considerable impact on the way plant-derived products are regulated outside the US. Exporters of raw material to the industry in those countries have to comply as well in order to stay in the market. Are you prepared?

Quality cannot be tested into a product. It always starts with good raw material and is transferred through a well documented production process into the finished product, which remains of high quality over a certain shelf-life time. cGMP above all is a lot of paperwork, documenting every aspect of the production process. Proper records must be established, maintained, and preserved in order that all aspects related to quality are traceable and transparent.

From an analytical point of view cGMP includes important statements:

- Each raw material must be tested for identity. Also purity and potency have to be determined.

- Appropriate and scientifically sound testing methods should be employed.

High Performance Thin Layer Chromatography (HPTLC) is the analytical tool of choice when it comes to rapid and reliable identification, detection of adulteration, and the establishment of batch to batch consistency and shelf-life of products. CAMAG, the experts for solutions based on HPTLC, provides all you need for this technique.

HPTLC is the TLC of the 21<sup>st</sup> century featuring:

- [cGMP compliant instrumentation](#) (Click on the links)
- [standardized methodology](#) and
- [validated methods](#)

The technique is described in the general chapters of the US, European, and Chinese Pharmacopoeias. Currently the most comprehensive approach to quality of botanical raw materials is found in the [series of AHP monographs](#). All of those monographs feature state of the art HPTLC methods for identification, which were developed by the CAMAG Laboratory.

**WORLD LEADER IN PLANAR CHROMATOGRAPHY**

CAMAG · Sonnenmattstr.11 · CH-4132 Muttenz (Switzerland) · [www.camag.com](http://www.camag.com)