

# Gooding Company Incorporated

## Firm Benefits

- Successfully completed customer audits in targeted industries
- Gained several new customers after passing customer cGMP readiness audits
- >90% of business shifted to Pharmaceutical & Medical Device industries

## Internal Auditor Training GMP Refresher Training

Gooding Company Incorporated (Gooding) is a specialty printer that manufactures printed package insert/ outserts and instructions for the pharmaceutical, medical and consumer markets. For several decades the 130 year old company primarily competed in the local, commercial printing market. Due to the extremely competitive nature of this industry, the company's management recognized a need to pursue a different strategic direction that offered growth potential and was not considered a commodity business. The medical and pharmaceutical markets were identified as a primary opportunity that met the company's strategic criteria.



Gooding's bindery team member, Doug Schoelles, Jr., folds pharmaceutical Inserts, counting and setting them into packaging sleeves..

However, in order to effectively compete in these markets, Gooding would need to meet specific and stringent industry requirements and regulations. Some of these requirements mandated expertise in the area of Quality Systems—specifically with the knowledge of FDA-regulated industries.

Over the last several years Gooding has effectively penetrated these markets and has experienced steady business growth. The company now employs 32 people and conducts manufacturing operations on a three-shift basis within a modern state of the art facility in Lockport, NY. This success is based on Gooding's reputation for on-time delivery and overall customer satisfaction and support. This positioning strategy has been effectively marketed through its registered trademark as the "Insert/Outsert Experts®", which further emphasizes their position as an industry leader.

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"Insyte Consulting provided the expertise and training necessary, 1st to keep all our personnel up to date with cGMP requirements and changes, a yearly requirement within our quality system. And 2nd, Insyte provided specific training in audit techniques for our internal audit which solidified our ability to verify compliance of the quality system with Gooding personnel. Insyte truly supported our progression within the pharmaceutical marketplace."

Gerald Hace, President

Insyte Consulting  
726 Exchange Street  
Suite 620  
Buffalo, New York 14210  
phone: 716.636.3626  
fax: 716.845.6418  
email: info@insyte-consulting.com  
web: www.insyte-consulting.com

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### Situation

Gooding's ability to access the medical and pharmaceutical market was directly linked to its compliance with specific quality system requirements, particularly cGMP (current good manufacturing practices) of those industries. Although the company first became compliant in 2006, specific activities needed to be maintained in order to remain in conformance with the standard. Insyte Consulting was contracted to assist Gooding's personnel to become familiar with cGMP and to ensure that these activities became part of the culture and procedures within the company.

### Solution

The first initiative provided internal auditor training for selected employees. It was determined that this process would be an excellent way to introduce Continuous Improvement throughout the organization while adding knowledge of customer requirements for bioscience products. The training was completed using a formal quality system structure and ISO 9001:2000-based internal auditing requirements. Management has continued to support the internal auditing process by continuing to train additional employees due to internal staffing changes.

The second initiative was a company-wide presentation to put perspective on the role that every Gooding employee plays as a supplier to a medical device or pharmaceutical product company. The various facets of the company's operation were covered so all employees would have familiarity with the principles characterized in cGMP industries and that customer specific requirements would be met. Management proactively supported these programs with strong participation that demonstrated commitment to the cGMP process and how this activity supported the overall mission and strategic direction of the company. These programs were supplemented with annual refresher presentations in cGMP for all employees. This satisfied a cGMP requirement to keep all employees current regarding cGMP applications and usage.

### Results

Gooding has successfully completed several audits by customers in the medical products and pharmaceutical industries. They have realized new business as a result of their ability to understand and comply with cGMP requirements and meet or exceed customer expectations. By 2007 Gooding had successfully shifted its business mix to over 90% medical device and pharmaceutical business. This represented a successful implementation of the strategic direction pursued by senior management several years ago.



Gooding's bindery team member, Beverly Hayward, observes a high tech Global Vision Camera counter that is certified 100% accuracy for their pharmaceutical customers.