

WE ARE A SERVICE-DRIVEN ORGANIZATION FINDING UNIQUE SOLUTIONS TO OUR CUSTOMERS' GMP CHALLENGES



by **ACETO**

About Us

A&C has been servicing the life sciences industry since 1966, with offices and GMP production facilities in North America and Europe.

A&C is a global GMP manufacturer of excipients, buffers, process ingredients and a select number of APIs.

We are a service-driven organization finding unique solutions to customers' GMP challenges.

Our Services Include:

- GMP Custom Ingredient
 Development & Manufacturing
- GMP Manufacturing
- GMP Custom Packaging

www.acggp.com



We are trusted for:

- Our Quality Focus
- Our Flexibility & Responsiveness
- Our Partner Service
 Organization Approach

As a Partner Service Organization, all of our teams work in unison to solve our customers' GMP challenges through innovative and personalized approaches.







A&C can fulfill the need for custom or novel raw materials through a practical process development approach.

Our R&D team has over fifty years of experience in problem-solving and utilizes one of the world's leading project management tools to provide cost-effective, robust and timely solutions for all of our partners.

Should a customer require a specific excipient or other raw material to be manufactured within a fully compliant GMP process, A&C offers this service with transparency and full supporting documentation.

Once the process developed by A&C is completed and validated, the product is manufactured, packaged and released under full GMP compliance.



A&C offers a variety of custom packaging formats that meet FDA packaging requirements and batch-specific container sizes for both liquids and powder raw materials. Volumes and specifications are defined to meet customers' specific requirements. Product packaging is completed in an ISO Class 8 cleanroom environment. Product is delivered

on approved pallets, wrapping and/or outer rigid containers. Packaging formats range from 100 ml to 1.000 L. and include:

- Glass Bottles (Clear & Amber)
- ✓ Plastic Drums HDPE (Various Formats)
- Stainless Steel Drums (Various Formats)
- ✓ Single-Use Bioprocess Bags



A&C is renowned for our high quality standards and provides full transparency in the supply chain, which is vital for compliance with GMP and GDP. We provide regulatory support for all products by having a detailed supply chain statement (available upon request). Customers are notified of significant changes through a strict change control program.

We hold all the major certifications and applicable licences from the main accreditation bodies and agencies:

- √ ISO 9001:2015
- **☑** EXCiPACT (GMP and GDP)
- Drug Establishment Licenced for manufacture of APIs







A&C has developed the Partner Service Organization (PSO) approach for our customers. Technical support is available throughout the sales cycle, from initial enquiry to full-scale GMP production.

Understanding our partners' needs from the start allows us to find unique solutions to their specific issues.

A&O's global GMP manufacturing facilities allow us to complete a variety of projects simultaneously with rapid response and completion times. Thanks to our PSO approach, our partners experience R&D, project management, GMP documentation and production lead times that surpass the industry norm.

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