

# ***Audit Program***

*Experts in GMP audits for  
clinical and commercial  
manufacturing operations*



## Smart Consulting Group – Audit Program

All the GMP-type audits are provided by our company to support both clinical and commercial manufacturing operations.

### Our services include the following types of audits:

- Supplier/vendor audits/program support, including raw materials, API and components
- Facility audits including: older site GMP audits for FDA/EU/ICH compliance, including internal assessments and mock regulatory agency audits of third party CMO audits for contract manufacturing
- Testing laboratory audits, including third-party testing and stability; this includes chemical, microbiological/cell culture and physical attribute testing
- Companion internal QA-type quality audits

### Our audit program covers the following product categories:

- Pharmaceuticals
- Biopharmaceuticals
- Vaccines
- Solid dosage drugs
- Creams
- Medical devices
- Liquids, sterile and non-sterile
- Device drug combination products
- Vitamins and dietary supplements
- Neutraceutical manufacturing
- Cosmetics/cosmeceutical manufacturing



Our audits are completed by professionals with greater than 20 years' experience in the industry. Our auditors include both industry and former FDA veterans.

### We supply a comprehensive approach to our audit programs, including:

- Pre-audit review of documents
- On-site audit sessions complete with data feedback and post-audit roundup meeting
- Detailed post-audit written report which includes observations/findings and recommendations
- Post-audit assistance with remediation actions, if required
- Work breakdown structure/project management plan

We can service large and small audit requirements, so let's discuss what your program needs.

**Call us at 610-344-9218 to find out more.**

