

## Good Manufacturing Practices (GMP) Guidelines 2009 Edition (GUI-0001)

On May 8, 2009 Health Canada published updated Good Manufacturing Practices Guidelines for DIN registered products. These revised guidelines include modified and/or new terminology, the incorporation of most GMP questions and answers, additional requirements such as annual product quality review, additional interpretations and an updated table of requirements.

This new document becomes effective for most changes on November 8, 2009. Some of the key and important changes that you should be aware of are;

### C.02.011 – Manufacturing Control

The addition of a new requirement for Annual Product Quality Reviews, the scope of which includes;

- Regular periodic or rolling quality reviews of all drugs.
- A review of critical in-process controls, finished product testing results and specifications.
- A review of all batches that failed to meet established specification(s) and their investigation.
- A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventative actions taken.
- A review of all changes carried out to the processes, analytical methods, raw materials, packaging materials, or critical suppliers.
- A review of the results of the continuing stability program and any adverse trends.
- A review of all quality-related returns, complaints and recalls and the investigations performed at the time.
- A review of adequacy of any other previous product process or equipment corrective actions.
- The qualification status of relevant equipment and systems (e.g., HVAC, water, compressed gases, etc.); and
- A review of agreements to ensure that they are up to date.
- Quality reviews may be grouped by product type (e.g., solid dosage forms, liquid dosage forms, sterile products, etc. where scientifically justified).
- The quality control department of the importer or distributor should ensure that the annual product quality review is performed in a timely manner.
- Where required, there should be an agreement in place between the various parties involved (e.g. importer and fabricator) that defines their respective responsibilities in producing and assessing the quality review and taking any subsequent corrective and preventative actions.

### C.02.006 –PERSONNEL

The new requirement for an importer, and distributor that the individual in charge of the quality control department

- Hold a Canadian university degree or a degree recognized as equivalent by a Canadian university or Canadian accreditation body in a science related to the work being carried out.
- Directly controls and personally supervises on site
- Persons to which Quality Control manager may delegate duties and responsibility (e.g., to cover all shifts) has a diploma, certificate or other evidence of formal qualifications awarded on completion of a course of study at a university, college or technical institute in a science related to the work being carried out combined with at least two years of relevant practical experience, while remaining accountable for those duties and responsibility.

The document may be viewed and downloaded from:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0001-eng.php>