Drugs and Health Products

Letter to Stakeholders - Responsibilities and Obligations with Respect to the Good Manufacturing Practices

Health Canada reminds drug manufacturers about the importance of good manufacturing practices (GMP)

On February 17, Health Canada sent a letter reminding all Drug Establishment Licence (DEL) holders of their regulatory responsibilities and obligations when it comes to maintaining good manufacturing practices (GMP). The letter advises DEL holders that Health Canada intends to increase the frequency of planned and unplanned inspections of facilities, where necessary. More frequent inspections will help Health Canada take timely and appropriate action.

Health Canada is also making more information publicly available about its compliance and enforcement efforts. To that end, the Department has posted an Inspection Tracker: Drug Manufacturing Establishments. This tracker provides a regular snapshot of the potential health and safety issues Health Canada is tracking with companies that make, package, test, wholesale, distribute or import drugs for sale in Canada.

Letter to Stakeholders - Responsibilities and Obligations with Respect to the Good Manufacturing Practices

Health Product and Food Branch
Inspectorate Program
Graham Spry Building, 2th floor
250 Lanark Avenue
Address Locator #2002A
Ottawa, Ontario
K1A 0K9

February 17, 2015

To: All current Drug Establishment Licence Holders (DEL) and new DEL applicants

Re: 1) Responsibilities and Obligations with respect to compliance with the Good Manufacturing Practices as set out in Part C Division 2 of the *Food and Drug Regulations;* and 2) Health Canada's ongoing transparency initiatives

The purpose of this letter is to emphasize the responsibilities and obligations of Drug Establishment Licence (DEL) holders including new DEL applicants for both active pharmaceutical ingredients (API) and finished dosage form products. Furthermore, this letter serves as notice that in light of the some of the concerns discussed below, Health Canada's compliance and enforcement activities may impact the frequency of planned and unplanned inspections as well as unplanned onsite visits for the purposes of compliance verification.

Observations - General:

Health Canada conducts inspections regularly within Canada and globally and works closely with international regulatory partners, who also perform inspections in Canada and internationally. During inspections, observations are noted by Health Canada inspectors and / or our trusted regulatory partners. Health Canada expects regulated parties to promptly action the resolution of observations made during all inspections, including those of our regulatory partners.

Observations - API:

The *Food and Drug Regulations* were amended in 2013 to extend the requirements of Establishment Licensing and Good Manufacturing Practices to the manufacturing and importation of APIs.

During recent inspections focused on activities related to API, Health Canada has noted a number of issues in the areas of traceability (supply chain integrity), vendor qualification, cleaning validation, data integrity and packaging conditions and has taken compliance and enforcement actions, where appropriate. Health Canada expects that all regulated parties demonstrate adherence with the Good Manufacturing Practices (GMP) by ensuring processes, systems, training and expertise of employees are meeting the GMP regulatory requirements.

Observations - Data integrity:

The integrity of data is an underlying expectation in the regulation of health products and establishments and any related issues have the potential to cause significant risk if not addressed. Data integrity issues have recently been noted in several facilities domestically and globally. Health Canada continues to monitor these issues and expects regulated parties to provide information as requested while also demonstrating how the integrity of data is ensured in their facilities as well as any facilities with which they are linked through contractual agreements.

Transparency:

Transparency initiatives related to inspections are a key priority for Health Canada. Initial transparency initiatives have involved posting lists of inspections and ratings as well as summary report of inspections resulting in a non-compliant rating. Beginning April 1, 2015, GMP inspections will be summarized and posted as part of Health Canada's Openness and Transparency Framework. These summaries will be posted as soon as possible following the onsite inspection or review of GMP evidence, prior to the rating being finalized. If changes occur following the initial posting of observations, the posted version would also be updated. Health Canada is also planning increased transparency regarding on-going issues related to health products and establishments, building on the transparency initiatives that were launched in late 2014.

In summary, Health Canada's primary objective is to help protect the health and safety of Canadians. As regulated parties, all parties conducting regulated activities play an important role in helping to achieve this objective. The points above highlight areas of particular current concern. Any deficiencies related to the above points may result in increased oversight by Health Canada.

Date Modified: 2015-02-27