

Kualifikasi pemasok dan ketertelusuran rantai pasokan = Supplier qualification and supply chain traceability

Ana Uswatun Hasanah, author

Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=9999920522270&lokasi=lokal>

Abstrak

Industri farmasi harus mematuhi CPOB untuk memastikan bahwa konsumen menerima obat yang aman dan bermutu tinggi. Mutu obat tergantung pada bahan awal, bahan pengemas, proses produksi dan pengendalian mutu, bangunan, peralatan yang dipakai dan personil yang terlibat. Setiap industri farmasi memiliki rencana strategis atas kualifikasi terhadap pemasok. Evaluasi prosedur kualifikasi terhadap pemasok bahan baku dan ketertelusuran rantai pasokan yang dilakukan di PT Darya-Varia Laboratoria (DVL) dilakukan untuk menilai prosedur kualifikasi pemasok dan ketertelusuran rantai pasokan. Evaluasi dilakukan dengan observasi terkait pelaksanaan kualifikasi pemasok di PT DVL Tbk Citeureup plant. Kualifikasi pemasok di PT DVL Tbk Citeureup Plant meliputi seleksi pemasok, assessment (melalui kuesioner atau audit), approved (memasukan ke ASL), dan peninjauan periodik. Proses kualifikasi pemasok telah dilakukan sesuai persyaratan CPOB 2018. Untuk memastikan ketertelusuran rantai pasokan, semua bahan baku harus berasal dari pemasok yang telah terkualifikasi/disetujui sesuai persyaratan CPOB 2018. Selain itu, periksa dokumen pendukung pada saat penerimaan seperti surat jalan, PO, nomor batch dan lainnya untuk memastikan kebenaran bahan baku yang dikirim.

.....The pharmaceutical industry must comply with GMP to ensure that consumers receive safe and high-quality medicine. The quality of drugs depends on the starting materials, packaging materials, production and quality control processes, premises, equipment used, and personnel involved. Every pharmaceutical industry has a strategic plan for the qualification of suppliers. Evaluation of the qualification procedures for raw material suppliers and supply chain traceability carried out at PT Darya-Varia Laboratoria (DVL) was conducted to assess supplier qualification procedures and supply chain traceability. The evaluation was carried out by observations regarding the implementation of supplier qualifications at the PT DVL Tbk Citeureup plant. Supplier qualification at DVL includes supplier selection, assessment (through questionnaires or audits), approval (submission to ASL), and periodic reviews. The supplier qualification process has been carried out according to the 2018 CPOB requirements. To ensure supply chain traceability, all raw materials must come from suppliers who have been qualified/approved according to the 2018 CPOB requirements. In addition, check the supporting documents at the time of receipt such as travel documents, POs, batch numbers and others to ensure the correctness of the raw materials sent.