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COLLECTION OF GMP-DOCUMENTS FROM THE SWEDISH PHARMACEUTICAL INDUSTRY

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There have been several international acquisitions and mergers of the Swedish pharmaceutical industry during the recent 20 years. Headquarters and management were successively moved abroad. As a consequence, the archives of the companies have been moved or sorted out as well. Thus, we will lose an important source for future research.

The Academy found it essential to initiate a project in order to collect documents for a new archive with GMP- and quality-related items. The documents will be selected as examples of drug manufacturing as it was made during different time periods and under current GMP-requirements. Examples of documents which will be collected are those which are required by GMP or quality systems. The GMP of EU requests about 100 documents of that type, which should be followed or issued during manufacture and quality control.

We have established contacts with major manufacturers and most of them have opened their archives for us. We expect to collect or copy about 2000 documents covering the time period 1940 - 1999. Two simple Excel books are used and any future researcher will easily have access to documents. The documents will be stored on paper as we believe that scanned documents will be difficult to read within 50 – 100 years.