COLLECTION OF GMP-DOCUMENTS FROM THE SWEDISH PHARMACEUTICAL INDUSTRY.

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Let me start with a similar story to the one I am going to talk about. Can anyone tell how these pyramids were built? (2,3)

I am standing upon one of them and I am looking south. (4) There is The Sfinx who may have the answer. Can he tell? (5,6)

We should probably know how they built the pyramids if someone had saved documents from the construction work. (7)

- Project plans
- Drawings or lay out
- Specifications
- Work plans
- Manufacturing methods
- Material supply
- Labour data
- Machines and equipment

Hopefully we could read it from papyrus rolls 4600 years old. (8)

We have realized a similar problem in Sweden – not connected to one of the seven wonders of the world – but important enough to get some attention.

Just a few years ago the Swedish pharmaceutical industry had two huge, international companies – Astra and Pharmacia. Both of them had a substantial manufacture in Sweden and more than 90% of production was sold on export.

Astra has merged with Zeneca and major parts of manufacturing has been sold off or moved to China and India.

Pharmacia is almost erased after the acquisition by Pfizer.

The export of pharmaceuticals from Sweden was sometimes our biggest export-income. Bigger than Volvo cars, steel and paper.

Sweden found it important to take an active part in the harmonization of manufacturing rules like Good Manufacturing Practice. It was very important to obtain mutual recognition of inspections.

Sweden was a member of trade organisation EFTA and EFTA initiated mutual recognition of inspections and elaborated a common GMP quite early.

Headquarters and management now have moved abroad. As a consequence of that also the archives have been moved and sorted out. Documents describing a golden era will be lost and future historic research will miss them.

In order to try to save some documents the Academy of Pharmaceutical Science initiated a project.
The purpose of this project is: (9, 10, 11)

- Establish a historical collection of documents representing the development of manufacturing and quality control for industrial production of pharmaceuticals in Sweden

- The collection will include examples from different time periods 1940 – 1999

- The records will be catalouged and filed such as to benefit future historical research.

We will not only collect unique documents rather the trivial simple things which no one would save for the future else. Documents should be related to manufacturing or quality control. We will select only examples by random. There is no intention to pick a complete set of documents from one single company. We would rather have small and big companies represented as well as different dosage forms. We aim at collecting some 2000 documents covering the time period 1940-1999.

Documents will be stored as Xerox-copies. We belive that such copies will last for at least 100 years if archived correctly. We abandoned electronic scanning as we think that documents scanned today will be difficult to read within 100 years. Paper or papyrus is much more stable.

If you look into the GMP of EU you find more than 100 paragraphs were there is a need for some kind of documentation. (12) We took that as a parameter and we will categorize all documents to fit into one such requirement. This is than registered in a simple Excel-file. We call this the MATRIX (13) There is one page for each of the 9 chapters of the GMP and there is also space for the age of the document. Each decade from 1940 to year 2000 has got its column.

We collect a document. (14) We put an id-number on it and register in another Excel-file in accordance with the same GMP-requirement.

Next step is to put the id-number in the other Excel.file, which we call the REGISTER. (15) Correct line and year-column. The document is thereafter archived in number sequence.

If someone in the future wish to look for a specific document and find out how GMP was interpreted he looks in the MATRIX. He finds an id-number and may find some more information in the REGISTER before the actual document is picked out from the archive.

At the moment we have established good contacts with all Swedish manufacturers. All of them have been helpful but unfortunately some of them have already moved or sorted out the older documents. Another source is the inspection reports from the Authority. They are public after twenty years.