

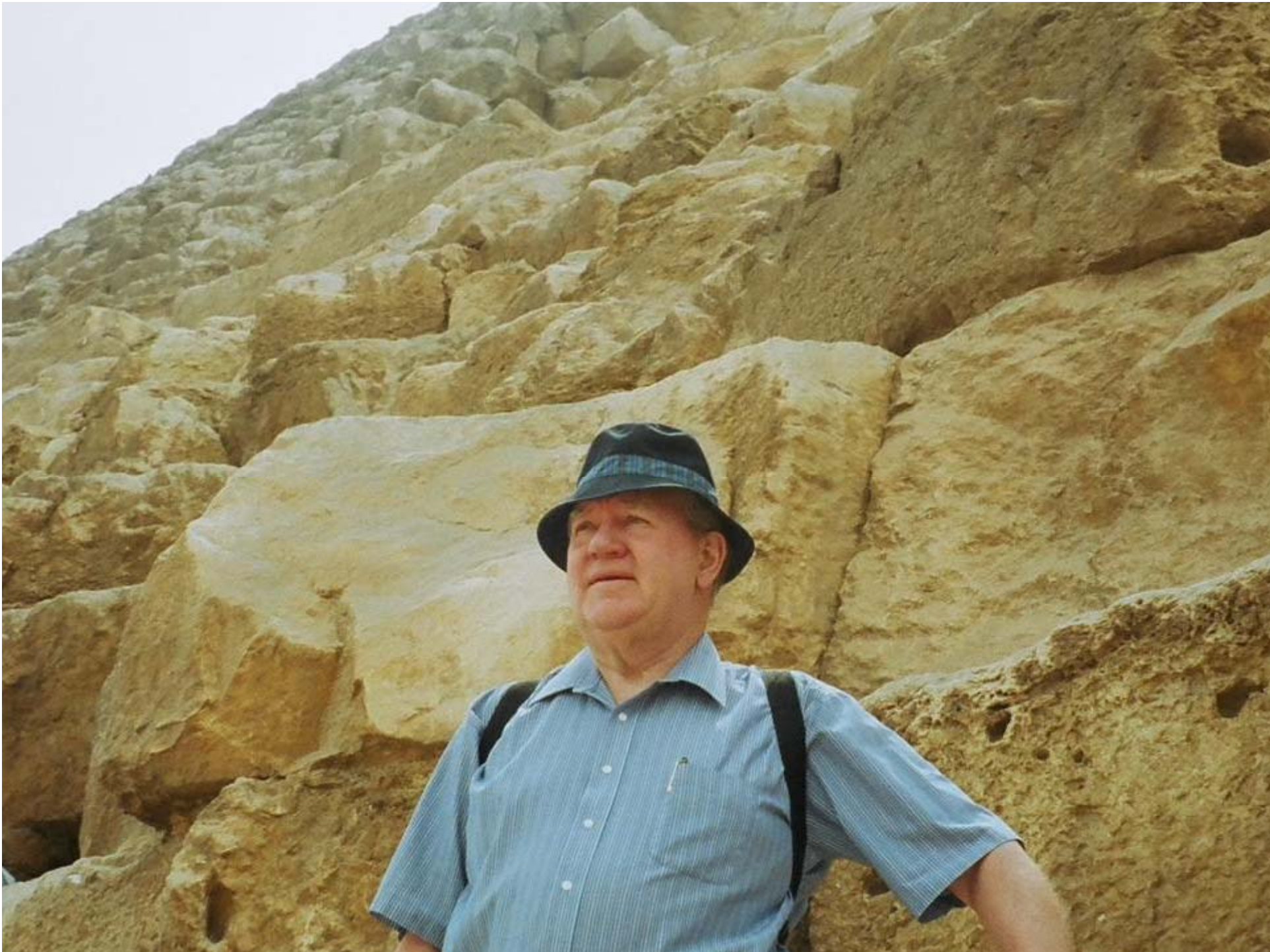
**Collection of GMP-documents**  
from  
**the Swedish Pharmaceutical Industry**

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Can anyone explain how these pyramids were built?









What do the SFINX know?

# Can he tell us.....

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

On papyrus  
from  
4600 years ago





# Purpose

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

# Objective

- The collection will include examples from different time periods 1940 – 1999
- The records will be catalogued and filed such as to benefit future historical research.

# Things to do

- **System for filing**
  - 2 Excel-files
    - REGISTER
    - MATRIX
- **Collect the documents**
  - From participating companies
  - From inspection reports
  - From other sources

# EU - GMP

- Has got 9 chapters and 18 annexes
- Requirements for documentation
  - Before, During, After manufacture
- Over **100** such requirements
- Chapter 4: *Good documentation constitutes an essential part of the quality assurance system*

**Matris 4.  
Dokumentation**

**MATRIX**

Dokumenttyp	< 1950	1950-1959	1960-1969	1970-1979	1980-1989	1990-1999	Kommentar
4. SOP för upprättande av SOP							
4. SOP dokumentstyrning							
4. Specifikation råvaror							
4. Specifikation förpackningsmaterial							
4. Specifikation halvfabrikat							
4. Specifikation bulk						303	
4. Specifikation slutprodukt							
4. Tillverkningsföreskrift							

An Example of a Document

'94 03/22 15:52 46 8 6565345 PEPTIDE HORMONES 303:4 @002

KONFIDENTIELL

Pharmacia  
Kabi Peptide Hormones

Title	PURCHASING SPECIFICATION (P.S.)	Page	1 (4)
Product	Two chamber cylinder, boxpacked	Number/date	499-446-03/94-03-22
		Replaces number	499-446-02
Controlled by date and name	<i>A. Breunig</i> 22/03/94	<i>B. Hjertman</i> 940426	
Manufacturer/Supplier	<i>M. Åslund-Koch</i> 940324	<i>I. Fransson</i> 940324	
	M. Åslund-Koch, QA	I. Fransson, Purchasing Department	

**QUALITY REQUIREMENTS**

Manufacturing and control shall be in accordance with requirements in ISO 9001.

**Material**

The cylinder is to be manufactured from neutral Schott tube glass (without the coloured line) which meets the specification for glass type 1 in Ph Eur, USP XXII and Ph Japan.

**Colour**

Colourless.

**Resistance to water**

Tested and requirements in accordance with ISO 720.

**Measurements and tolerances**

According to Kabi Pharmacia drawing no. 499-446 C.

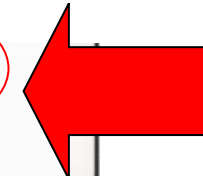
**Sampling plan**

Military Standard 105E level S4 and II is used.

**Batch classification**

A batch is understood to mean the number of cylinders that have been manufactured during a set of time period and related to Kabi Pharmacia's Purchasing order. Cylinders manufactured on different lines and shifts must be identified. It shall be possible to trace the tubular glass batch through the batchnr.

Be.



ID-number

# REGISTER

Farmacihistoriska sällskapet								
Projekt: Kvalitetsdokument/Läkemedelstillverkning								
Löpnr	Antal sid	Dokumenttyp enligt matris	Årtal	Företag	Fyndplats	Reg. Dat	Signatur	Kommentar
303	4	4. Specifikation bulk	1994	Pharmacia	LV	20090902	LE	

