Exhibit 189

Pfizer refused to serialize its SARS-CoV-2 injections, even though it was a legal requirement

Hedley Rees

https://hedleyrees.substack.com/p/pfizer-refused-to-serialize-its-sars

Hedley Rees is a zealous advocate of modernization in the Pharma Industry, as well as being Managing Consultant at PharmaFlow Limited, a UK based consultancy specializing in operations and supply chain management in life sciences. Assignments range from early stage clinical trial supply chains to complex multi-product supply networks covering global territories.

Prior to this, he held senior positions at Bayer UK, British Biotech, Vernalis, Ortho-Clinical Diagnostics (a J&J Company) and OSI Pharmaceuticals.

Hedley graduated from the University of Wales as a production engineer and holds an Executive MBA from Cranfield University School of Management.

He has authored two books on Pharma industry modernisation, 'Find It, File It, Flog It' (2017) and 'Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics' (2011).

Pfizer refused to serialize its SARS-CoV-2 injections, even though it was a legal requirement


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Aug 26

What is Serialization?

Serialization is a mandatory requirement in the pharmaceutical industry. It was introduced in order to protect against counterfeit or other misbranded products entering the legitimate supply chain.

This article, Serialization in the Pharmaceutical Industry, provides useful information, including this extract:

The precondition for protection against counterfeit medicines is to produce a barcode (2d data matrix) that gives all production data (GTIN [Global Trade Item Number], expiration date, lot number) for one unit medicine. This distinctive marking ensures the authenticity and integrity of the medicine so that the manufacturer ensures that all the medicines are protected from intervention."

Note the reference to ***one unit medicine.*** This means that the manufacturer must apply a 2D barcode to every unit of finished product produced and upload their manufacturing information to a central database. As the product moves through the distribution to patients, the barcode can be scanned and checked for authenticity, or not.

A subscriber made the connection

I was aware that this could not have happened with the Pfizer and Moderna vaccines, because they left the manufacturer frozen and in vials containing 5 doses, not a single dose. What I didn't know was this comment in the Newsletter below, from a subscriber

“‘“Curious to note the leaked Pfizer contract(s) state "the F Member State acknowledges that the Vaccine shall not b

Read more here, or skip on:

INSIDE PHARMA

ALL ABOUT LOTS, TOXIC OR OTHERWISE

WHAT DO THE REGULATIONS SAY ABOUT LOTS? The FDA cGMP definitions can be found here. Below is a definition of a lot (batch) and lot number Lot means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits…

Read more

7 months ago · 6 likes · 9 comments · Hedley Rees

FDA definition of batch and batch number

Now we need to go onto FDA definitions:

Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

Hedley explains with the help of wallpaper (recording):

1.0× 0:00 -6:31

Key takeaway

The mRNA vaccines were only part-finished, and not unit doses, when they left the manufacturer, so could not have been serialized. They also had to bypass the long-established wholesale distribution networks in the various countries, because they were not geared up for frozen or ultra-frozen temperatures. These wholesale distributors must have licenses, based on compliance with Good Distribution Practice (GDP), before they are allowed to operate. This all amounts to gross non-compliance with safe working practices, in place to keep patients safe from errors and malintent.

Where have FDA, EMA and MHRA been?

13 Comments

Cheryl Grainger 12 hr ago ♥ Liked by Hedley Rees

Over time reports have been given about the vials being kept at -70oC and kept at special units that could cope with these temperatures and then as time went by there didn't seem to be the need for temperatures so low?

Were the vaccines designed like this to get around GDP?

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3 replies by Hedley Rees and others

JLo2112 11 hr ago ♥ Liked by Hedley Rees

Aside from the mRNA technology, this was my biggest concerns about the shots. Quality