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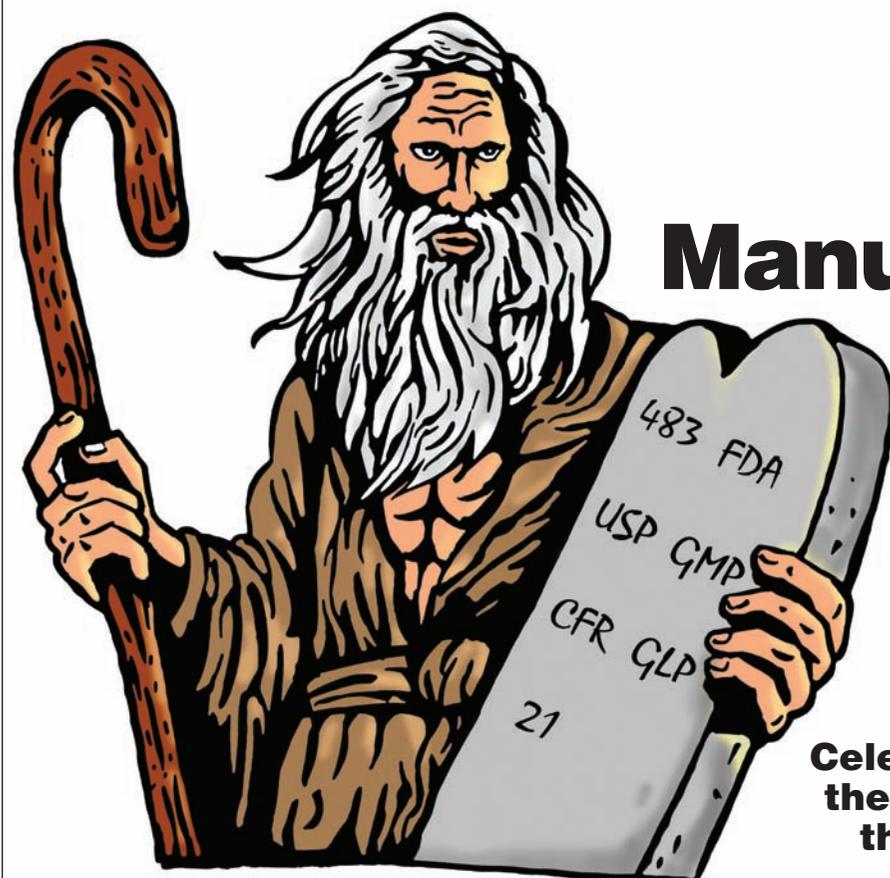
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PREVIEW ISSUE

THE GOOD BOOK OF MANUFACTURING PRACTICE



The Good Book of Manufacturing Practice

**Celebrating — in parody —
the King James Bible and
the Sherley Amendment**

By **Herbert N. Prince and Jason W. Prince**
Gibraltar Laboratories

FOUR HUNDRED YEARS AGO, IN THE YEAR 1612, the King James Bible was made available to the literate British public and those of the clergy and crown who could read. Those of us in the pharmaceutical industry mark another anniversary — it is 100 years since Congress enacted the Sherley Amendment, which prohibited the labeling of false claims. These two events — one of which has promoted spirituality for people of many faiths and one which has made the protection of man's health a proper role of government — deserve to be celebrated. Return with us in parody and style to the stern and minutely detailed regulations of the Old Testament as if they were regulations promulgated by today's FDA. In this way we celebrate these two remarkable events . . .

Nehemiah's Wall - The Wall of Quality

Now whosoever pursueth manufacture of salves, ointments, medicines, as it is set forth (Isa 38:21; 2 Kings 2:21), or cosmetics (Prov.7:17, 27:9; Exod. 30:35; Ps 45:8) is required to make a master schedule, a complaint file, put up a Tent and then build a wall around the plant like was builded by Nehemiah when he came back from Babylon to teach the Law. The complaint file must tell all that is known about the plant concerning deviations in the manufacture and not only what is found good. This is the law. It must be told the side effects to tell your doctor even if rare and unlikely such as causeth the patient who has died to disappear. This is so — do not laugh — it is writ-

ten in the Federal Register December 8, 1950, 133:1100; October 4 1953 127: 202, 37243; and January 30, 1955 133: 45325 and CFR 21 part 158 subsections 586 to 721, which are things about training, calibration, adulteration, misbranding and divers other things that may cause the warnings, recalls, seizures or other things that peradventure can put the president in jail who knoweth not about mice in the warehouse — this is so.

Now the Wall that is builded will keep out products of poor quality such as might come from the Great Sea who are a warring and powerful people who have forsaken the rules and statutes of the people from the River which is the people West of the Great Sea who are a manufacturing people who do not follow the Mediterranean Diet which is mostly olive oil and tilapia and nuts but a people who eat a lot of meat — if it is killed the right way — this is so.

The Wall and the Master Schedule will favor those who follow the law, do what is right in the eyes of what is — much told from the inspectors, maintain a production without blemish

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else a great cloud will come upon the Tent and stir up the dust of the earth — as it was in the beginning.

Law of Disobedience — A Rebellious Worker

Now it came to pass that in the fifth month, which was the seventh year of the reign of Dr. Amfortas, which was the very serious European businessman with a scientific background that was come to New Jersey to fix a company which had a pipeline going the wrong way that he found out that in the company was a stubborn and rebellious worker (and others) who did not hearken to the rules, nor the SOPs, nor what is right in the eyes of the FDA. His superiors lay hold onto him and bring him to the twelfth floor and say unto the Elders up there:

"This worker is rebellious and stubborn and reads not the SOP of the aseptic fill or even anything else down there or even anything about the small volume parenterals which are hard to make and which are in short supply and with a terrible profit margin and the Congress is screaming about. He keeps needles and syringes in his pocket, which is not told in the SOP, and removes his hairnet and contaminates the place. Our son is evil and does risky things, fears not the power of the law, and is a danger to the work. He does these things."

"Can now our medicine and our needles and syringes suffer the misbranding and adulteration?"

"Yes."

"What sayeth thou about his personal life, this evil man up here before me on the twelfth floor?"

"He has most strange and offensive ways in his household, in his garden he plants two kinds of seeds, the coriander and the olive, last harvest the grape and the barley. God forbid. He does other evil things such as wearing linen and wool on the same shirt such that send at least four score and twenty particles equal to or greater than 0.5 μM in diameter in the air, every second (we counted them). In the laboratory there exists a great abomination when he makes on the same shelf the 0.85% sodium chloride of the inorganic side with the 62.0% w/v of the organic germicides approved by the FDA but not by the EPA, this is so."

That he and his kind mayest fear the awful and powerful name of the Law they took him out of the city, like in the book by Franz Kafka that Dr. Amfortas told them. They read him a letter written by Ezra the scribe, the son of Ephraim, who is the brother-in-law of Phineas, who is a friend of Nehemiah who was the cup-bearer to the King of Babylon during the captivity of the consent decree, which is a warning that he has five minutes to live. He is blindfolded and turned around 17 times. He is then tripped and as he stumbles he says, "Why dost thou trip a blind man?"

This is the law of the SOP. "He doesn't recant. He sleeps with his fathers."

Of the Germs

Of the germs within the water, the environmental surfaces, mucous membranes, skin, or divers parts of man's body that has affliction — *these you may kill*.

The germs of the swellings which are the boils on the arms or drainage in the throat that cometh from the staphylococcus

or even the streptococcus and what hath been called the "UTI" (which makes much soreness in the man and the woman) and divers others of the pestilence that are come amongst you, upon you — from you — with vinegar or red wine you may kill them — they are a danger — the germs also which have the resistance to the MRSA which is much ado about nothing because no one uses this anymore — this is so, do not laugh — these you may kill — also the germs of the leprosy like the TB which are from the soil or from people in the camp who lie in very closeness together — and the markings of the diagnosis are very real to the eyes of Aaron the physician who is the son of Rheoboam who was married to the daughter of Teva or Mylan, or whosoever in the camp knows the signs and symptoms of these afflictions — *do not try vinegar or red wine*, for they will not work, no, they will not work — the germs are too strong for them — but you must look like to the molecules of the Dead Sea or elsewhere, or perhaps to the soil for another antibiotic like that was got by Dr. Waksman for Streptomycin when he got the Nobel Prize many years ago. That you may be prosperous in manufacture, take note and study the nature of the creatures of pestilence. Find them, isolate them, for it is a good thing to kill them — a very good thing.

Of the bacterias that abideth in the milk of goat, cow or other animal which cheweth the cud — *these you may not kill*. When the milk is sour and comes with curd which is clear at the above it is from the lactic acid bacteria which make the D- or the L-isomer of this metabolite — these you may not kill for because they are the probiotics which remove cramps from the

More Wisdom from the Bible

Medicines

Isaiah 38:21 – "For Isaiah had said, Let them take a lump of figs, and lay it for a plaister upon the boil, and he shall recover."

2 Kings 2:21 – "And he went forth unto the spring of the waters, and cast the salt in there, and said, Thus saith the Lord, I have healed these waters; there shall not be from thence any more death or barren land."

Cosmetics

Prov. 7:17 – "I have perfumed my bed with myrrh, aloes and cinnamon."

Prov. 27:9 – "Ointment and perfume rejoice the heart: so doth the sweetness of a man's friend by hearty counsel."

Exodus 30:35 – "And thou shalt make it a perfume, a confection after the art of the apothecary, tempered together, pure and holy"

Psalms 45:8 – "All thy garments smell of myrrh, and aloes, and cassia, out of the ivory palaces, whereby they have made thee glad."

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stomach and bowel and are good. They are a blessing to you — do not kill them — no, do not do that to them — and you can make cheese from them — this is true, do not laugh — and the cheese which may cometh from the milk and the bacteria therein will nourish your kinsmen, the stranger, the widow and even the orphan which may come before thy gate — as it is said, let them alive — it is a good thing.

The Law of the *E. coli*

If a food or medicine has the *E. coli* in it then it is unclean unto you and must be destroyed, yea even unto every batch in the plant of the manufacturing. When the plague of the *E. coli* is in the food of any sort or the medicine that is taken by mouth at sundown or anytime then it shall be brought to the lab and, behold, if the serological group O15:H7 of the hemorrhagic colitis from a pig is found or any animal that does not chew the cud or cleaves the hoof or does not cleave the hoof but chews the cud is found in the lab, the thing must be told to the Director of Quality Control and then to the King. The King shall then see if the food or medicine has been shipped into the pipeline and then do the thing called the “recall” and tell the Government and then the *New York Times* before the Government does this. The *New York Times* will leak this thing to Nathan or to either Samuel I or Samuel II — it makes no difference but not to Amos, Hosea or Isiaiah or even Ezekiel because they have not been born and will make plenty of their own trouble when they start complaining and predicting about other things in the future.

When Nathan or Samuel I or II tell the FDA they will send 15 men to knock on the gates and say “We are here to help you,” and, “We pray have you destroyed all the lots according to CFR 21 part 32 subsection 16?”

And answereth the lab, “But peradventure we find that 50 are good . . .”

“You may not keep them. Destroy them as a sin offering on any day but Saturday between 8 a.m. and midnight on the sixth or eighth day of any month that is good for you with a fire made of three parts hyssop, two parts willow, a sprig of myrtle even with the juice of one lemon — do not laugh.”

“Perhaps 25 lots can be kept for even with the plague of the *E. coli* it will surely die in the custom of Baal in the dry season and we will not ship them until the square root of something is calculated and given to a risk expert who will study the numbers and write a chapter in the USP and even so the active

ingredients are in spec and the pH is good.”

“You may not keep them.”

“Peradventure if we irradiate the lots to remove the blemish off the *E. coli*, let us say with 25 KiloGreys from the Cobalt-60?”

“You may not keep them.”

It came to pass that the laboratory did not hearken unto the words of the FDA and shipped the lots with dead *E. coli* and thus went to jail the Director of Quality, the King, and even the President and all the Vice-Presidents whom was told this thing is because what is written in the book of the law as told in CFR 21 Part 211 subsections 84, 113, 188 and 194. This is the law.

H5N1 - The Bird Flu

The likeness of any winged fowl that flyeth in the heavens or dwelleth in the sea or on the lake or pond may bear a pestilence within its flesh and blood and be a danger of health unto you. And further, as this pestilence stirs in the air and in the dust it may deal corruptly with other creatures that crawl or breathe in the air — as in the beginning was first breathed by man. It is the influenza. It was born on the farm. Take heed in the plague it may become — there is no vaccine — so sayeth the nations.

It pleaseth us to note that of all the animals that sojourn near or upon this pestilence, neither the likeness of the ox, goat, gazelle, calf or antelope, nor the lesser winged things that swarm upon the earth, are become sick. It is instead the pig and the chicken. They dwell together on the farm. So sayeth the nations of the earth, the journals, the WHO, the *New York Times* (International edition, February 18, 2012) — so sayeth them all. Of the greater and lesser animals of the waters, the air and the farms, who among all the creatures of the earth are most come to perish? It art the chickens.

So therefore take heed that this pestilence are much more greater than the leprosy which we knew when we were in the Wilderness of Zin, or the virus that causeth the diarrhea and vomit on the cruising boats in the Carribean or the bacteria that causeth the Montezuma’s Revenge — it is breathed into the nose like the ferret who dies in the Tent and the people who are afraid in the street, very much like the 1918 — and a child who sings of the coming plague:

“I had a little bird.
Its name was Enza/
I opened the window,
And influenza.” ■

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