Galenisys 11 rue Notre Dame de Nazareth , 75003 Paris, France. Tel : +33145554414 or +33632329927

January 2025 | NUMBER 46

NEWSLETTER

Tony Dunford Editor

In this Edition :

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

Happy New Year

to all our readers from the Galenisys Team

New Year, New Budgets, New Projects.

The Editor

Welcome to 2025. It's time to get going again. Whereas the sales people know that January will be a thin month, (particularly if they pulled forward some January sales to meet last year's target); for many of us January introduces a new budget year when we can really get moving and make some commitments.

Our article in the Project Management Managers Diary series, is focused on how to let a good contract. If economies in Europe are sluggish – GREAT - get out there & snaffle good offers for your project equipment.

If you're in Production or Quality Assurance, it's also time to get moving again. Make contact. Do a tour of the factory floor, and/or the laboratories to check that people are not still suffering from their parties. Are the packaging lines whirring happily? Are the incubators switched on?
Oh yes, also wish the boss a Happy New Year.

Then, have a coffee and check out the rest of your Galenisys Newsletter

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

The Project Manager's Notebook Part 6.

By Aubonne

There is a **lot to cover** when placing orders for equipment or services in a pharma project.

When structuring a project, there's benefit in breaking it down into “packages”. Placing contracts in this “work breakdown structure” (see the September 2024 Galenisys Newsletter) keeps them within the same technical & legal context. It helps to define “battery limits”, & ensure physical & digital compatibility, without overlaps or gaps in the overall project scope.

The checklist I used when I was responsible for **letting large project** contracts contained 24 different headings only one of which was “Terms and Conditions”. I'll deal with a few of these different contract items in this article.

Terms and Conditions should certainly define. Which law will go under contract? Where would be the? Place of Arbitration. Physical delivery point. Currency. For example. It's perfectly possible to have an, apparently adhoc mixture. (For example on large projects in francophile Switzerland, we successfully used French as the project language for Meetings & Minutes, English for the language of contracts, Swiss Norms for the specifications, Swiss francs for commitments & currency, and the place of (eventual) arbitration was London).

If the project has a **Quality Manual** this should be compatible with the Terms and Conditions, (or precedence defined). A Quality Manual can usefully be included as context, in the Invitations to Tender sent out to bidders prior to contract letting.

Supplier audits. These can be very useful precontract in order to establish whether a supplier, however keen, has actually got the capability to deliver. A competitive price is not sufficient.

Continued on next page ...

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

Payment Terms. Given the long lead times between placing an order and complicated items coming into service, suppliers can reasonably expect to receive a deposit. 10% - 25% is common. Progress payment(s) may be agreed for eg delivery to Site. But always retain a substantial final payment until after installation, qualification and acceptance. And consider penalty / bonus payments for items on the critical path.

Fixed Prices. Do beware of potential suppliers who are unwilling to offer fixed price contracts. If the package scope, specifications, and terms & conditions are clear, a viable and experienced contractor should have no difficulty accepting them. (If the supplier has reservations, check if he has understood the scope or has some surmountable reservation).

Project Risk. Package contracts should receive particular attention when there are risks to the overall project in the event of non-delivery or technical failure. As a result, these contracts should include the rights of inspection, ownership, & quite possibly the provision of an irrevocable bank guarantee.

Instruction manual & "as built" drawings. It can be a long time between project inception and the facility becoming operational at which point the Production QA and Maintenance teams take over from the Project team (who often disappear from sight). The instruction manual and "as built" drawings are essential "knowhow" parts of the handover baton and should be received before final payment.

If you need more help with aspects of Pharma Project execution, just give us a call, we'll be happy to assist.

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

"And Good health in 2025!"

This could be increasingly difficult to realise for many people.
The Editor

We spent Christmas in the UK, and as normal received plenty of Christmas cards. Many of them contained the usual **best wishes for our happiness and good health**. This latter looks to be an increasingly unrealistic wish globally.
I've noticed, over the past decades, the incidence of asthma has increased markedly. A large part of my manufacturing career focused on manufacturing products to combat the allergies caused by particulate contamination and polluted air.

It looks as though many of us in the life sciences industry will in future decades be addressing the problems caused by pollution.
Some 20 years ago a minky whale was beached and subsequently died. An "autopsy" discovered that its stomach contained approximately 1 tonne of plastic objects. These plastic objects were obviously of a visible size. But the pollution we are facing – detailed in alarming official reports** - is measured in micrometres and nanometres.

Continued on next page ...

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

These “nanoparticles” are the result of the breakdown of much of the 500 million tonnes of plastics currently being produced globally. This figure has doubled since the Minky whale died. 1/3 of this total goes into single use plastics and 10% into synthetic textiles. (One can add in some 6,000,000 tonnes p.a. of rubber particles from vehicle tyre abrasion to the contamination problem).

Unfortunately, less than 10% of the 500 million tonnes is recycled and currently 360 million tonnes are discarded - abandoned on land or sea where it degrades into the microplastics contaminating the soil, the water, the air, ... and all living things.
Extent to which human beings are being contaminated by plastic particles is surprisingly little appreciated when compared with the understandable concern about climate change.

Death by plastic?

We absorb these particles in food, and in the air we breathe (and in the creams we apply to the skin). Studies have identified nanoparticles in rice, bottled water and tea for example. And other studies have found them in various human organs such as the lungs, the colon, the kidneys, the testicles, and placenta, with our bloodstream ensuring the distribution to the brain and sensory organs as well.
There's no consensus currently on the typical amount each adult is carrying, however the view that everybody consumes approximately one credit card equivalent per week is likely greatly overestimated. Experts do estimate that a city dweller can inhale up to 100 million nanoparticles per year.

Continued on next page ...

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

These particles are only one part of the problem. The other is the 16,000 additives breakdown products or impurities which are found in various plastics. The additives are there to make the plastics more stable, resilient, flexible, appealing, or easier to manufacture. Unhappily, 1/4 of these are considered to be dangerous, or in some cases carcinogenic. The financial cost in USA of the illnesses caused by just three of these contaminants was put at $675 billion in 2010.

So, basically we're poisoning each other. (This is not a plot for Hercule Poirot - even he couldn't solve it easily. But national governments should continue to try)

Under the guidance of the **United Nations**, an international treaty is in the course of negotiation, to reduce plastic pollution. In the fifth phase of these negotiations last November, 170 countries got together to try to finalise a text. Unhappily this failed due to the refusal of certain petrol states (Russia, Saudi Arabia and Iran in particular), to envisage a reduction in their production of plastics!

It used to be that the doctor reported “he died of old age”. How long will it be before the Coroner’s Certificate states “he died of plastic”?

The 170 national governments need to earnestly continue discussions.

** Such as that published in November 2024 by a committee of experts reporting to the French Senate and Parliamentarians, with recommendations to guide future government policy.

“The Tamalou Tours”.

There’s nothing like an interesting ailment
The Editor

It was Rene our next-door neighbour in France who first told me about the **“Tamalou Tours”.**
Roughly translated into English **“T’as mal ou?”** equates to **“It hurts you where?”** However, this doesn't have the same cachet as the French expression. (“Cachet” ..... get it?).

Continued on next page ...

The “Tasmalou Tours” conjures up that familiar and credible vision, of the elderly generation setting off on a coach journey to some beautiful corner of France or the Rhine Valley, and spending the travel time discussing their various ailments.

Thankfully I don't have too many of these. And I guess I would be a passive participant at the end of the lunchtime gathering when the elderly pull out their box of assorted brightly covered & compartmented tablets, numbered by days of the week; for discussion, and even consumption.

Spare a thought for the medical professionals. It's quite likely that several of them have been involved in the prescriptions which built these collections.

Firstly, folks normally see their regular “Doctor”, “Medicin”, or “Physician”. Sometimes the dentist will also prescribe, and on holiday (Doctor Lib?) or abroad you may need treatment & new medication. And what about that stuff you decided to try after chatting to a friend and bought online?

Given the limited time the hard pressed medical corps have to devote to each patient now; (10,15, or 20 minutes per patient), it's difficult to cover in that time the whole range of illnesses and conditions a patient might present with, or indeed have, without knowing it.

From time to time, I see our retired next-door neighbour and have a chat with him in the street. He tells me about his current state of health, and the progression of his illnesses, one of which is daily kidney dialysis. At some stage other problems he has had resulted in a prescription of steroids that he continued to take.

This caused great consternation, when his dialysis specialist learnt this! So here we have our old age pensioner with perhaps six different concurrent treatments, the combination of which could potentially give a wide variety of contraindications, particularly if he or she, on top of that, has got allergies to, for example, avocado or grapefruit or peanuts, etc.

There's a lot to be said for helping the elderly with an inventory of the various treatments for their discussion with the regular doctor, to see if some rationalisation can take place. Less risk of adverse contraindications, even though there’s less to talk about on the holiday tour.