

NEWSLETTR

HAPPY NEW YEAR TO ALL OUR READERS

2023

Best wishes for the success of your plans & projects !

In this Edition :



GALENISYS FORECASTS FOR 2023

Fresh back from their break, we asked senior members of the team for their forecasts for 2023:

Firstly what they expect to happen in pharma, & healthcare broadly?

and secondly to spell out what progress & changes they would like to see in the year?

Tony Dunford Editor



ON-SHORING.....

IMMUNOLOGY.....

**LOCAL VACCINE MANUFACTURE
BOARD COMMITMENT**



By Steve Biddulph

Fellow of Royal Institute of Microbiology. Board level pharma experience. QSM and Aseptic Manufacturing & Control Expertise

I FORECAST THAT in 2023, we will see the trend of “on-shoring” become increasingly evident in the pharma industry. The shortages and supply chain disruption experienced during the epidemic have received widespread publicity. The problems continue in some areas & are fresh in the public’s mind. Greater impetus will come from public pressure. (It was notable that the early December protests in China against the excesses of the “COVID – ZERO” policy, was followed by an abrupt “about turn” by the Chinese Communist Party).

All Governments were under heavy pressure at the height of the epidemic, given the lack of PPE, vaccines, drugs & facilities for infected patients. I predict many Governments will continue to seek to establish in country vaccine manufacturing capability, (projects that Galenisys is already helping with).

Furthermore, no pharma company, having spent a decade or more getting its product to market, wants a wobbly supply chain, making onshoring increasingly attractive. However, this has to be balanced with the arguments for the economies of (manufacturing) scale, and “Centres of Excellence”



I ALSO PREDICT THAT The exciting breakthroughs in gene editing & other revolutionary research techniques will lead to the development of new strategies & potential treatments for autoimmune diseases, cancers, and “orphan diseases”.



Now, what would I like to see, (but may not see)? I WOULD LIKE a greater commitment by the governing Boards of big pharma to full implementation of Quality Assurance in the Development function

Steve Biddulph

PARTICIPATION by HUMAN BEINGS

By Colin Washer
Galenisys Board Member

Human beings have always looked forward, and so predictions are natural.

This year I FORECAST we will see a return to more social interaction and group activity. There is an enduring attachment to gatherings such as religious festivals, the farmers livestock market, the “Tapas Bar”, the welcome back of the winning team, the beer festival. It’s because these are things people can participate in.

In isolation, Covid induced or other, participation is limited & even impossible. The exceptional Chinese protests against the Covid restrictions demonstrates how much people need participation and the stimulation this brings.

At Galenisys, we look forward to working as closely as possible with our clients in 2023 & beyond, (and we will never send an AI enhanced robot to meetings with you!)



**COMPLIANCE STRESS
.....INSPECTIONS**

By Jose Zapata

Galenisys Pharma Senior Expert. Pharmacist with frontline experience in Quality, Operations & Project Management.
PDD Certified

"Nunca sabemos a ciencia cierta qué ocurrirá en el futuro, pero tengo fe en nuestro ingenio para hacer que las cosas se hagan".

1. Las compañías farmacéuticas con productos inyectables deberán evaluar y cumplir con el nuevo EU Anexo 1, que entrará en vigor de forma oficial en agosto de 2023.
1. Las restricciones en China por el covid continuarán complicando la producción y la cadena de suministro de los productos farmacéuticos. Europa internalizará más producción.
3. Las inspecciones de las Agencias regulatorias quedarán prácticamente normalizadas (excepto en China) tras el período covid, y presumiblemente las fábricas que no hicieron su trabajo durante este tiempo podrían enfrentarse con problemas.



1. Injectable Pharmaceutical companies will (wake up) and realise they have to assess, & comply with, the new EU Annex 1, that will come into effect officially in August 2023.
2. China covid restrictions will continue stressing the pharmaceutical production and supply chain. Europe will bring back more production inside.
3. Agency inspections will be almost normalized (except in China) after the covid period, and those plants that have not "finished their homework", risk trouble.

UK VACCINE MANUFACTURE CARE HOME VIABILITY



By Terry Simmons

Galenisys Technical Director. Extensive experience across many roles in Aseptic Manufacturing, the Supply Chain, & Project Management.

UK VACCINE MANUFACTURE We were all rightly elated when the AZ – Oxford vaccine proved successful in UK labs, & available from UK factories. The Government bought a pharma site in Wrexham to help cement future supply capacity.

Regrettably, I forecast that the 2020 -2021 momentum will (further) ebb away in 2023. We've heard little in recent months - apart from the Government selling the site to Catalent - who have put earlier plans for kitting it out on hold, "temporarily".



CARE HOME VIABILITY I hope that in 2023 there will clear plans announced to ensure that Care Homes capacity is increased, & that they become financially viable when providing the quality of care expected by the elderly.

The current issues are widely acknowledged & publicised: a shortage of staff & therefore capacity, relatively low pay, cash-strapped local Councils, the elderly who haven't saved enough, and a backlog of dischargeable patients blocking hospital beds.

The UK Pension Industry is obliged to invest in UK Gilts. Why also, can't it be obliged to invest in Care Homes. After all, its funds are provided by (the relatively richer) actual & future pensioners, who are also the future Care Home clients.

ALTERNATIVES and PREVENTION

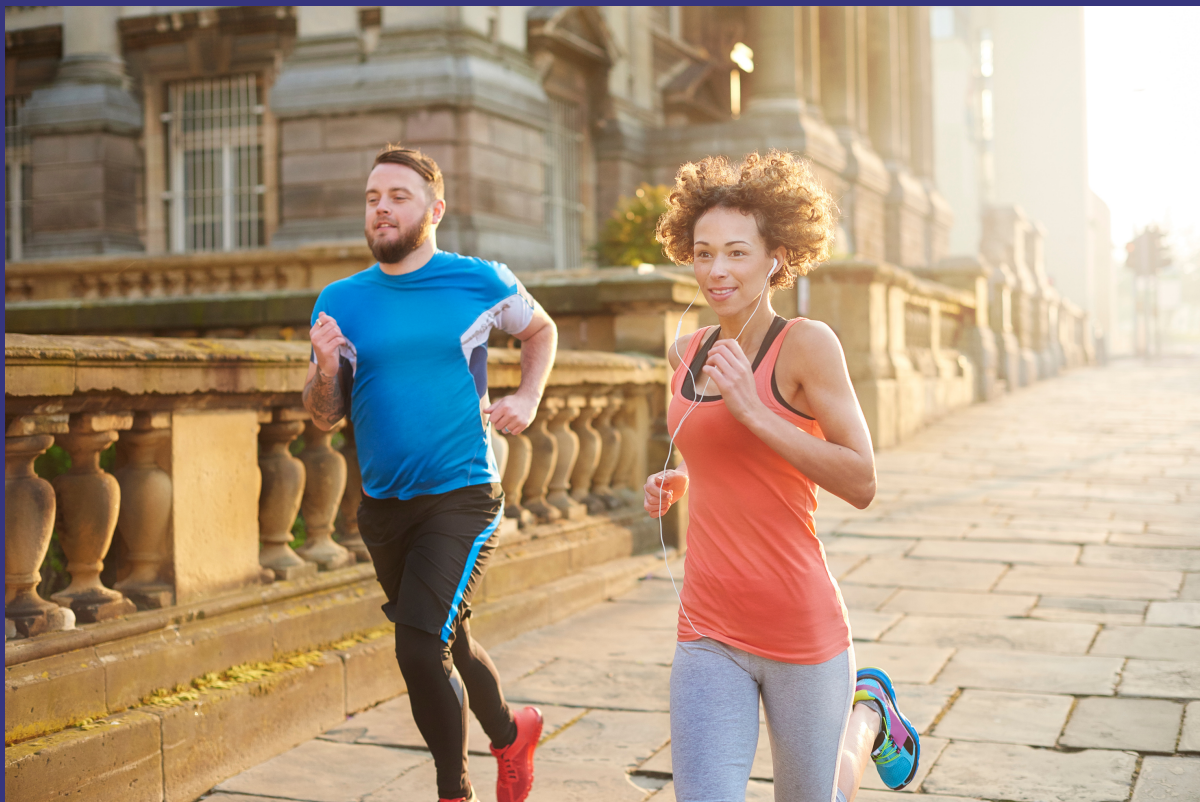
By Tony Dunford

Galenisys Business Oversight Director & Newsletter Editor

In many ways the backdrop in 2023 will resemble last year. Covid is still with us, (see article below) notably in China, and is still contributing to high hospital bed occupancy in Western countries.

Healthcare backlogs continue to be extensively reported, as Terry Simmonds has mentioned. As a result, I forecast an increasing use of private medicine, and for less serious illness or prevention, greater recourse to in Home Diagnostics, Health Wearables, Consumer Health products, Nutraceuticals, & Online Pharmacies.

Amongst long term trends, I hope that we will see people taking greater responsibility for their own and their children's health. Obesity, rotten teeth, and other indicators point to the need for more vigorous promotion of a healthy diet, exercise, & reduced alcohol consumption.



FORECASTS FROM ELSEWHERE..... VACCINES VVARIANTS

Adapted from The Economist

We now enter the 4th year of the Covid Epidemic. Significant new variants (ie more severe, or more contagious) have been arriving on average 2 per year. Unfortunately, apparent similarities to “ordinary flu” have caused some misjudgements. But flu is far less contagious & comes only in winter. Natural & vaccine immunity against a flu variant, lasts longer than the 3 months or so for Covid.

The PREDICTIONS of some scientists are for 50% of Americans to catch Covid this year (v 5-20% flu) with 100,000 deaths!

However, WE HOPE TO SEE some of the 170+ vaccines currently in clinical trials make it through to rollout. The key breakthroughs would be effective nasal vaccines and variant proof vaccines. A nasal vaccine potentially gives immunity in the 1st infection impacted cells, preventing proliferation in the individual, and in his contacts.

Yet other vaccines being researched, will be essential if a feared aggressively contagious & far deadlier variant turned up. Fingers crossed that it doesn't.

AI and CLINICAL TRIALS

By Hary Biddulph Galenisys Contributor

Vastly improved software empowers AI. I FORECAST that in turn AI will increasingly be used for pharma Research, & during Development as eg BioNtech has demonstrated. New techniques in new areas bring different human specialists together to improve communication & collaboration.

Even with the most technically assisted R&D, the benefit to human patients still has to be demonstrated in Clinical Trials. I HOPE there will be efforts to clearly demonstrate which approach(es), and model(s) in trial structure & management, favours effective recruitment efforts, greater engagement & improved retention, and thus overall trial optimisation.

