



# TRANSFORMATIONAL CHANGE TAKES TIME

QUICK FIXES ARE RARELY LONG TERM SOLUTIONS

by John Johnson

**Back in 2014, we were approached by a relatively small company in Eastern Europe who had been referred to us by an established client.**

GM Pharmaceuticals in Tbilisi, Georgia had an ambition to change itself from top to bottom and the goal was to raise standards across the Tbilisi facility, so that it could demonstrably meet WHO GMP guidelines and, at some later stage, meet EU cGMP expectations and host a GMP inspection from the European Medicines Agency. Why was this such a transformational change? At the time, there were literally no other major pharma manufacturing companies in the region and no local regulatory authority responsible for submissions, inspections and enforcement.

## SO, TO MAKE THIS DREAM A REALITY, WHAT DID THEY NEED?

Sometimes I find it easier to answer that question by turning the question on its head! What they didn't need:

- > A long list of known/unknown GMP deficiencies
- > People who would just tell them what to do
- > People who would just write the SOPs and GMP documents for them
- > People who would just say "it's impossible" or "it's easy" or other platitudes

What they needed was inspiration, collaboration, guidance, coaching, patience and a longer-term, supportive relationship.

Since then, over the course of nearly four years, we have been working with the team in Tbilisi at least three to four times per year and the wider team have supported the site through...



- > Training in:
  - Vendor quality assurance
  - Change control
  - Deviation management, root cause analysis and effective definition of CAPA
  - Cleaning validation and decontamination strategies
  - Facility design, commissioning, validation and ongoing monitoring
  - Management of stability studies
  - Investigation of suspected out-of-specification results
  - Training and qualification of lab analysts
- > Coaching in the preparation for, execution of and follow-up during various client and regulatory inspections



- > Mentoring of six to 10 of the team's critical position holders; providing on-site and remote guidance on how to interpret the cGMP expectations and how to deploy the resources available to best effect
- > Assembly of registration documents, position papers, goal setting and site objectives, as well as review of training records, training content and methods of verifying the effectiveness of training
- > Support to increase yield and output, and minimize reworking

Being on call is crucial. Being available and responsive at short notice has been key too, as life has a way of throwing up surprises at short notice. Time is never our friend in business!

## SO WHERE ARE WE NOW?

- > The site has rationalized its product portfolio, reducing complexity and cross-contamination risks.
- > It has improved its laboratories, layouts and utilities guided by our SMEs.
- > It has refined and simplified its policies and SOPs, making compliance more assured without adding ambiguity and complexity.
- > It is now facing the future with more confidence, expertise and experience interpreting EU cGMP.
- > It passes GMP inspections with fewer surprises and fewer GMP concerns.

## WHAT DID THEY SAY ABOUT US?

Our key contact, Eka Koplataдзе, Quality Director, wrote to us recently:

*"GM Pharmaceuticals has been cooperating with NSF and benefitting from its consultancy for several years. We have worked with nearly 10 consultants on different projects including technical as well as quality management system issues like upgrading of*

*production, validation studies, stability studies, risk assessment training, mock inspections, etc.*

*I would like to emphasize that GM Pharmaceuticals makes active use of services, trainings, audits, etc. from leading European consultancies, which enables us to make certain conclusions.*

*There are two main things which distinguish NSF from the other consultancies. The first is their excellent reputation. Any leading company and any successful manager who has any weight in the pharmaceutical industry has used NSF's consultancy or training services. It is true for the biggest leading firms all over the world. Even mentioning working with NSF promotes warmth and happiness on people's faces. They immediately start recalling their experiences with the consultants who have delivered the training course for them.*

*The second thing is the fact that the number of staff members in the room is continuously increasing while working with NSF experts. Staff members start preparing for working with NSF consultants a long time earlier and every minute is planned and scheduled with them. After working with the consultants, the actual project work starts at the company, which is an indicator for the management to evaluate the consulting service.*

*In addition to being experts in their own fields and GMP, all the consultants are amazingly pleasant; all of them share the character of having an incredible work attitude. Besides, they distinguish themselves with their brilliant communication with representatives of other countries and other cultures.*

*We are lucky and happy to have had the chance of working with NSF in the development of projects for our company."*

Someone once said there's more to GMP compliance than GMP; and though of course we "major" in GMP, we believe that our personal interactions, cultural awareness and long term relationships are what really make a difference.

Also see our webinar: **Using Behavioral GMP to Create Perpetual GMP Inspection Readiness.**



## ABOUT THE AUTHOR



John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms. He has senior operational and corporate-level experience in operations and quality assurance and has led multinational companies in strategic projects associated with:

- > Inspection readiness and remediation (in UK, Italy, France, Australia, Singapore, India and USA)
- > Crisis management including handling of regulatory authority actions, multinational recall and import bans
- > Major culture change to improve customer service, quality, cost or "on time in full"
- > Installation, monitoring and periodic effectiveness checks on site or company quality management systems
- > Paradigm shifts including downsizing, upsizing, mergers and acquisitions
- > QP development, training, mentoring and resource management
- > Lean projects in QC laboratories and OSD facilities
- > Management review and escalation processes from shop floor to boardroom level

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