No deviation is a solution provider for the pharmaceutical industry, and we are often asked what it means - as no one really wants to be a problem provider. As long as you are providing services, should you not be a solution provider?

Have you ever felt that despite people being very active and agitated, achieving their deliverables, presenting green KPI's… your problems don't go away? This is what we term *"managing in the wrong jungle"*.

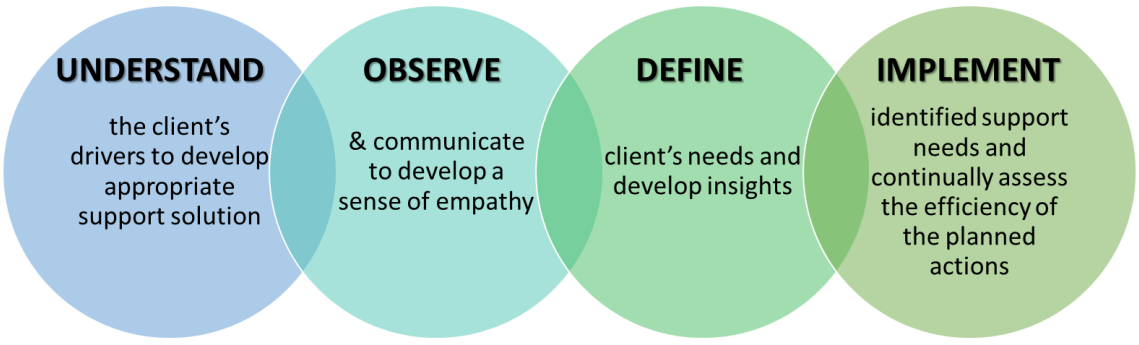
So how can we address it better?

How can we solve your problems, completely!

The approach of **"what you ask is what you get"** might be short-sighted. In this approach an action will be requested, and an implementation decided eventually, leading to several pitfalls. The requestor can only request what he or she knows, and it is assumed that the solution provider has an immediate and complete understanding of the request. This is without considering that maybe the initial request wasn't the right one, but we all know best what is good for us don't we…

To avoid this shortfall, in No deviation we like to develop a better **understanding** of **why** a request is made before addressing it. Once we understand the true reason behind the request and the problem to be solved, we will **observe** the context of it, what are the skills and resources required versus those available. We often paraphrase your request within a project charter - detailing our understanding of the problem by **defining** a step, or series of steps depending on the complexity of the issue at hand. Only then do we feel comfortable to talk about **implementation** of the defined solution. Very often this will take the form of an integrated approach i.e. leveraging from each others strengths in an interdependent way.

This standard approach is illustrated in the diagram below:



Once a problem statement is achieved it is important to keep the project goals in sight and manage activities in the correct sequence and order of priority. It is therefore important to identify and categorise those. The following picture is a convenient way to illustrate the different problem categories - "Four Types of Problems: From Reactive Troubleshooting to creative innovation - by Art Smalley"

1	2	3	4
trouble-shooting	gap from standard	target condition	open-ended
caused reactive		created proactive	

In order to achieve efficacy and efficiency we have developed tools and knowledge based on the deep understanding of the cGMP regulation and high-level principles described in the ICH Q8/Q9/Q10 coupled with Project management and lean thinking.

Developing a culture focusing on the patient safety is the key to achieve accountability in product quality from which compliance will be derived. This is achieved by growing a set of behaviours where risk assessment, quality by design and value creation is at the heart of the implementation.

By applying the above, our teams have managed to:

- Reduce the number of deviations by 5-fold on the site to which they were engaged
- Avoid an HIV drug shortage in Africa by delivering that project on time.
- We've also supported some of the biggest green field Biopharma developments in Asia and Europe.
- Help some of the smallest companies to become international players.



As we customise our solutions to your problems there is always a good reason to work together.

If you wish to find out more about us , fee free to drop us an email at admin@nodeviation.com or you can visit our website at www.nodeviation.com.