Process Deviation Management, Change Control, Capa

| Company: | known multinational pharmaceutical |
| Industry: | Pharmaceutical industry |
| Target: | Support the "Quality Assurance" department in process deviation management, change control and CAPA (Corrective Actions Preventive Actions) |
| Solution offered: | Quality & Operation Consulting |

1. THE STAGES OF THE PROJECT

Due to an increase workload, the client company had the need for specific support in the area of Quality Assurance management of the following processes:

- Process deviation
- Change control
- CAPA (Corrective and preventive actions)

The project involved the involvement of consultants with proven experience in Quality Assurance, gained in various sectors, including chemical and microbiological testing.

After an initial analysis of the business processes of the Customer, some team members focused on reducing deviations in process that were already ongoing, working closely with the entire company organisations to find the necessary information and draw up the relevant report, in accordance with the internal procedures of the Customer.

After the excellent results obtained reducing deviations that were already ongoing, the focus turned to new deviations.
The team drew up targeted investigation plans using effective CAPA and thus contributed to the achievement of two important objectives:

- Completing the investigations within the allocated time
- Reducing the root cause at the origin of the most commonly encountered problems

The resources involved in the management of change control and CAPA collaborated with the departments involved for the following activities:

- Preparing the necessary reports and documentation for the proper management and completion of activities
- Drafting operational procedures
- Intensive monitoring of production

2. STAGES OF THE PROJECT

In the early stages of the project, the customer company had already achieved two key results:

- Reducing to zero the number of deviations not closed in the allocated timeframe
- Increasing the number of new deviations closed without extension by 30%.

The contribution of S4BT Specialists in the Change Control Management and CAPA activities was crucial, because it allowed:

- The workload of the Internal Resources of the Customer (who were able to focus more on routine production activities) to be reduced
- The time required to properly manage (and close) the Change Control activities to be reduced
- Really effective CAPA to be implemented