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THE QUALITY CONTROL OF THE PHARMACEUTICAL INDUSTRY: THE CONNECTION DEPARTMENT BETWEEN THE PRODUCTION OF THE DRUG AND ITS ARRIVAL ON THE MARKET

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The Quality Control Department [1], in the pharmaceutical industry, is undergoing a wide transformation in line with the evolution towards Industry 4.0.
No longer just "data production department" but a deeply interconnected structure with all the corporate structures: the support develops at the level of the entire production cycle of the drug from the control of raw materials, to that of the environments, to the finished product ready to be distributed on the market.
It is a leading role of the "investigations" even among the most intricate (anomalous data, complaints from the market) and is now able to do all this in a "lean" perspective with attention to time and costs.
Finally, it is the department where latest-generation technology, automation and "paperless" concepts lend themselves to being tested and possibly implemented in compliance with the strict regulations in force.
For that reason, the analytical techniques supporting such as complicated department should support fast and repeatable tests, be as much as possible automatable with the respect of budget constraints.

References

[1] EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines