

# R&D Nearshoring to Eastern Europe

## Nearshoring Concept

Offshoring or outsourcing to offshore regions is frequently a cost cutting exercise. Quite often it turns out to be just that – cost cutting but not cost saving. Low costs for R&D activities due to low labour costs simply evaporate once the overall picture is taken into account: lower productivity, tremendous travel costs, logistic and legal issues and overall hassle due to cultural clashes and different time zones.

Offshoring	Nearshoring	In House
Significant cost reduction	Cost reduction	Costs well known but potentially high
Significant cultural differences	Less cultural differences	Similar cultural background
Direct contact requires time and effort	Reduced or low effort for direct contact	Straightforward direct contact
Significant time zone differences	Minor or no time zone differences	Usually identical time zones
Legal ramifications need to be considered	Similar legal systems (EU)	Legally secure
Quality standards may differ significantly	Similar quality standards	Quality standards defined
Logistics potentially costly and troublesome	Logistics reliable and reasonably priced	Logistics reliable and straightforward

Nearshoring is about avoiding all the offshoring drawbacks while going for true cost saving. The initial costs, e.g. daily rates, may not be competitive with Asian service providers but the Total Costs of Activity (TCA) are!

## What We Do for Clients

In short, HENRICH Pharma R&D-Consulting turns the Nearshoring-Wheel for our clients.

We use our expertise and our standing in Eastern Europe to drive client projects to value and to success. Our clients save up to 40% of the costs compared to the US or Western Europe. Our clients gain improved productivity up to 100% compared to Asia. Our clients operate safely under the legal umbrella of the EU. And our clients avoid the problems and hassles typical for offshoring to Asia: cultural clashes, nightmare travel, extreme travel costs, logistic problems and so on.

We select the right partners, we define, plan and run projects and we transfer the generated results to the client in an efficient manner, matching the requirements of progressing projects in time and with a quality that is fit for the intended purpose.

## True Story

A Western European Pharma company, client of an Eastern European API Service Provider faced an unwanted and unanticipated development problem. One compound of the late clinical portfolio was required by authorities to enter additional ADME investigations, including dosing of humans with radiolabelled compounds. To make matters worse, executive teams of the client had decided that the labelled material should be produced under GMP conditions. The time line for delivery of the material was less than 6 months and a supplier meeting the requirements was not available.

*Total Cost of Activities*

*Competitive Price in Combination with Quality of Service*

*A True Story*

1  
 **PERMANENT**  
Nearshoring to Eastern Europe

Upon the client's urgent request, the Eastern European Service Provider decided to support and developed a strategy to solve the problem. The existing GMP structure of the Service Providers production plant was to be transferred to a small existing lab unit running synthesis of labelled compounds for discovery purposes. The problem of cross-contamination from the decades old lab infrastructure was to be solved by application of isolator technology – which of course was not available at the starting point.

The Eastern European Service Provider ordered a glove box on the US market, promised by the supplier to be available fast enough to keep the time lines and promised to be fully GMP compliant as well. Based upon the original planning, project time lines at the starting point were tight but doable.

However, planning went down the drain when the US supplier was supposed to deliver the glove box, due to an almost grotesque reason – the isolator in its wooden transport box did not fit into the cargo hold of the airplane. Several weeks later, the US supplier finally identified a plane large enough but one which sadly did not touch ground anywhere near the Eastern European Service Provider. The desperately needed glove box ended up on a large Western European airport and had to be transported by truck to its final destination, where it arrived without any of the necessary and promised GMP documentation.

Even though timelines were practically out of reach already, the Eastern European Service Provider went to work and managed to deliver two miracles. First, by having key people in synthesis, analytics and QA working over Christmas and New Year's Eve they managed to deliver the labelled compound in time and in spec.

The second miracle became apparent during an audit performed by the client some weeks later. In the desperate dash to bring a non-compliant piece of equipment to meet GMP requirements, the Service Provider had generated a constant stream of GMP documents, SOPs, qualification reports, training documents and so on for weeks without producing a single GMP critical issue in the process. Even so the release dates of some documents were just minutes apart, the trail was faultless and passed the audit with flying colours.

Few Service Providers would have taken the initial risk of the project, few would have invested significantly on behalf of a client but very few would have pulled that project through in such a convincing way and against such odds.

## *Disaster striking*

## *Zero Compliance Issues*