

# TRAC – About Us

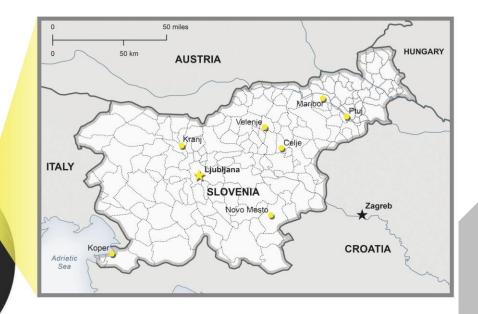
**Company Presentation 2018** 







- A family owned company
- Located in Šentjernej, Slovenia (EU)
- More than 25 years of experience in the pharmaceutical industry
- Continuous expansion into new regions and other industries
- More than 30 employees
- Enjoying what we do!









- A unique solution provider for complex technological processes in the field of:
  - CONTROL and
  - AUTOMATION of production processes
- Mainly active in the Pharmaceutical, Chemical, Biotech and Food&Beverage Industries
- Specialized engineering teams developing leading edge control automation engineering solutions
- Offering completely **customized** solutions!













#### A Dedicated Team

- A dedicated team that dedicates its entire focus on your project
- We are an enthusiastic team that enjoys technical challenges
- A performance-oriented team with ingrained group cohesiveness
- A complete solution provider for complex technological processes in highly demanded industries
- We strive for continuous improvements
- Your challenge is our solution!







## Our Company Values

All members of Trac team **possess a united vision** of the company **and its values!** 

Our values are a major part of our company culture! We share our company's values and actively work towards upholding our values!

We are curious and innovative!

We are honest and transparent!

We are passionate!

We are courageous!

We are flexible!

We are **ONE**. One **team**.







#### TRAC Global Presence

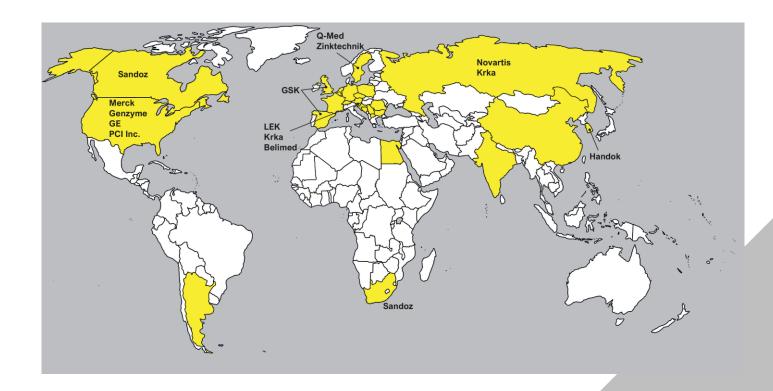
We are a **global player** 

We are **present** on **most continents** 

We **understand the needs** of local and global players

We think global and act local

We work together with the **main global** pharmaceutical **players**!





# **OUR STRATEGY** is continuous development and improvement in order to be able to design and develop new automation solutions within different industries. We strive to be recognized within an industry as a unique, reliable developer and trustable solution finder!



## What TRAC can offer you...

We turn your challenges into solutions!

Modular Concept

- The TRAC engineering team is equipped to deliver from complex turnkey automation projects to short-term fixes and problem-solving solutions
- All solutions are customized to specific customer challenges or needs
- TRAC's portfolio in solutions&services and own product development:



# SOLUTIONS SERVICES PRODUCTS Technology transfers Design Services: - Conceptual designs Process optimizations - Basic designs

Continuous manufacturing Turn-key automation

Equipment remediation

- Detail designs







TRAC

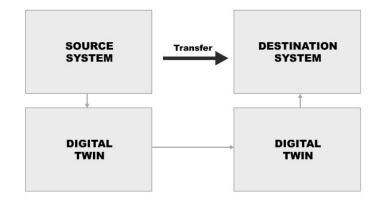
Technology transfers are very common in pharmaceutical and other high-tech industries

Companies are often forced to **consolidate** their operations or **optimize productions** 

**Automation** can play a **crucial role** in optimization and time technology transfers

TRAC's **unique** and **innovative solutions** are created on a digital twin source system

TRAC uses mixed reality, artificial intelligence, and high performance computing in a **Digital Twin Process** 









## **Process Optimization**

Main purpose - to **shorten** the overall **batch production time**!

Compared to the classical Finish-To-Start our concept saves immensely overall batch production time

TRAC strongly recognizes **Artificial Intelligence (AI)** as one of the crucial technologies for process optimization in the future

TRAC already uses part of AI technology in **our software solutions** to:

- increase throughput,
- identify process bottlenecks,
- improve logistics and
- evaluate potential process changes in manufacturing process - to shorten the overall batch production time.

#### **PROCESS FLOW**

|                  |                    |                      |            | Optimization     |                       |                      |            | Optimization     |                    |                      |
|------------------|--------------------|----------------------|------------|------------------|-----------------------|----------------------|------------|------------------|--------------------|----------------------|
| Cleaning<br>FLCV | Sterilization FLCV | Solution preparation | Filtration | Cleaning<br>FLCV | Sterilization<br>FLCV | Solution preparation | Filtration | Cleaning<br>FLCV | Sterilization FLCV | Solution preparation |
|                  | Cleaning<br>FV     | Sterilization<br>FV  | (CV > RV)  | Filling          | Cleaning<br>FV        | Sterilization<br>FV  | (CV > RV)  | Filling          | Cleaning<br>FV     | Sterilization<br>FV  |
|                  | Batch 1            |                      |            |                  |                       |                      |            |                  |                    | Batch 3              |
|                  |                    |                      |            | Batch 2          |                       |                      |            |                  |                    |                      |

CV = Compounding vessel, FL = Filtrate line, RV = Receiving vess







## Modular Concept

**Automation systems** made by TRAC are designed and built in a **modular way** 

Our own designed systems are built on **standardized** and proven **modules** 

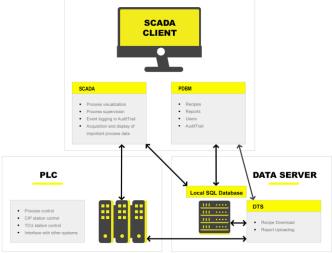
Our systems are easy to maintain!

We offer a system with very **fast, cheap** and **safe** possibilities for changes, modifications or upgrades

TRAC automation systems use **different modules**:

- PDBM (Process DataBase Management)
- DTS (Data Transfer Service)
- PLC
- SCADA
- Hardware











Continuous manufacturing is a **way** for **optimizing development time** and ensuring a faster commercial supply

With our approach and technology, we make your production leaner and more time-efficient!

TRAC uses different technologies to optimize and automate the process

- PAT (Process Analytical Technology) and
- QbD (Quality by Design)

as a fundament for real-time release!











## Design Services

TRAC enginering provides a complete turn-key production designs:

#### - Conceptual Design

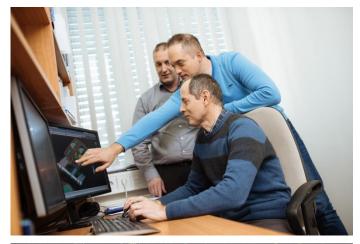
→ Includes a feasibility study, a high-level documentation and the first cost assessment of the project

#### - Basic Design

 upgrade of Conceptual design including economical, financial, infrastructural and geological studies and analysis

#### Detailed Design

→ includes a complete documentation ready for the project execution









## Turn-key automation

TRAC provides **specific** integrated **Turn-key** automation solutions

We utilize the **solutions** with our **standard software** and **design tools** or we develop a **customized software** 

We deliver a **complete Turn-key solution** for automated systems

**Examples** of Turn-key solution stages:

- list and diagram of all technological processes
- definition and selection of all active elements and sensors
- preparation of the extensive documentation that includes all stages of the project life-cycle (xDS, DQ, FAT, SAT, CC)
- installation of the automation system on-site
- start-up of the system
- IQ and OQ qualifications
- support with the PQ execution
- and MORE

TRAC with Turn-key automation delivers **key benefits** and **advantages** in the optimization of production time and resources









**Compliance** of the equipment and production processes according to the regulation is **crucial** 

**Legacy equipment** and **processes** have to be **upgraded** to fulfill the latest **regulatory requirements** 

TRAC has substantial **experience in remediating** the equipment and processes

**Examples** of remediation process steps:

- implementation of the new Recipe, Reporting, User management, Audit trail system (CFR 21 part 11 compliance)
- replacement of the existing small OP or command knobs with stateof the art SCADA system
- link to the existing MES system for a central production control
- replacement of the existing PLC with a new one

Equipment remediation is one of the most cost-efficient solutions to comply with the required regulations and adds additional value to the existing equipment!











#### **Products**

#### **BT100 Blister Tester**

OWN design, development and manufacturing!

TRAC has designed and developed a great and unique blister tester accepted in the most challenging high-tech industries

BT100 is a perfect **test equipment** to test the cohesion of packed strips, blisters and small sachets

Completely automated process and print outs

Operation based on vacuum / water seal

Reliable and proven technology

Easy handling



















| <b>1992</b> since                                       | <b>815</b> happy clients   | 980<br>finnished projects   |
|---|--|---|
| over 25 years experience in the pharmaceutical industry | understanding and development of software programs and solutions | successful complex and high-<br>tech projects in different areas: |



API plants
Weighing applications
Sterile solutions preparations
Oral Solid Dosages
Washers
Remediation Projects

Aseptic Drug Preparations
Clean Media Preparations
Liquids, Cream, Ointments Preparations
Dispensaries
Equipment integration
HVAC systems

AND MUCH MORE...

Microbiological cabinets
CIP and DIP units
Docking stations and new solids
LAF Cabinets
Drying Chamber
Dedusting unit







# Why TRAC?





- Unique and highly flexible solution provider in control and production automation processes
- Direct communication to the solution architects and implementors
- Dedicated team only to your project
- Specialized teams in different areas
- Own know-how and training center
- **Discovering** and **adopting** new upcoming technologies (as an example, Artificial Intelligence)
- Innovating new technologies and solutions
- Proven history of successful projects
- References with international known and high-tech companies
- Reliable partner



## We are READY for your CHALLENGES!



Knowledge, Skills and Passion. Knowledge, S and Passion. Knowledge Skills and Passion. Knowledge, Skills and Passion. Knowledge, S and Passion. Knowledge Skills and Passion. Knowledge, Skills and Passion. Knowledge, S and Passion. Knowledge Skills and Passion. Knowledge, Skills and Passion. Knowledge, S and Passion. Knowledge

#### Some References





cinfa

**★** cellufuel



TARO

ALKALOID SKOPJE





PLIVA

Q-MED

a Sandoz company

(Sp) lek





Roche)

SUN

















(H|F)





















































**III** Mylan







**BOSNALIJEK** 







Knowledge, Skills and Passion.



"Building a strong partnership with our customers is crucial for success of the projects"

Tomaž Rešetič, CEO

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Contact Us for any additional information or clarification!

