



Smarter Solutions
for Enduring Value



Design
Manufacture
Commission
Qualify

ABOUT US

DDE is constantly working to provide smarter technologies, systems and solutions to healthcare companies. For the last 30 years, our focus has been to develop smarter innovations. Today, DDE houses 350+ engineers, technicians, designers, biotechnologists, researchers and experts working at the intersection of technology and healthcare sciences to solve some of the industry's toughest problems.

OUR VISION / MISSION

To lead the global industrial footprint with distinguished solutions and be a partner in growth for our customers. With exceptional customer focus and astute project management skills our mission is to bring inspiration and ingenuity to everything we engineer. We aim to enhance the credibility and success of our customers through our reliable path-breaking systems and equipments by being as future-oriented and diversified as the industry in which we operate.

THE WAY FORWARD

We are redefining boundaries in the high purity business while working with sterile formulations, bio-pharmaceuticals, vaccines and MDI industries.

We have positioned ourselves to be the world's smart sterile systems manufacturer by envisioning smarter ideas, greener technologies and solutions.





Process Engineering



Automation



Plan



Qualification & Validation



Design Engineering



Training



Manufacturing



After-Sales Support

SMARTER PROCESSES



We understand that creating solutions for any industry's toughest challenges not only requires current wisdom to be harnessed but also investment in smarter future-proof technologies and processes.

Our processes are creating enduring value for our customers and are driving advancements in the domain of protection. This approach is helping us address customer needs more efficiently and effectively.

Driven by an in-depth understanding and domain expertise, we are contributing to the global pharmaceutical industry to play a pivotal role in improving countless lives.

We hear you

Your vision is at the center of our process roadmap. With proactive dialogue and exchange of ideas, we identify critical factors for performance and analyse your requirements.

We plan + design

Our team of hand-picked experts plan and design your project with highest attention to detail. We propose smart turnkey solutions that are reliable, cost-effective and in compliance with prevalent regulatory requirements.

We partner throughout the project life cycle

Our advanced manufacturing processes involve the industry's best in class techniques and knowledge accrued over the years.

We implement quality assurance systems for consistency and a thorough check across our manufacturing and automation process to ensure complete aseptic design of our solutions .

We partner with you for installing and validating systems to ensure a quick qualification for minimized time to market.

We work closely with you through your entire manufacturing lifecycle with our training and after- sales support.

To offer these life saving equipments, we follow all engineering and quality standards. This can be seen through our long-standing association with the world's best and biggest pharmaceutical companies.

We are your product custodian

Your satisfaction and trust are our performance parameters.

At DDE, we don't just execute a project, we ensure highest quality and consistency to deliver **smarter solutions for enduring value.**



SMARTER INDUSTRIES



Bio-pharma

- Cell Culture / Microbial / Bio-Enzymes
- mAbs / Biotherapeutics Blood Plasma, Biosimilars / Nutraceuticals, Pro-biotics

Vaccines

- Viral - Bacterial
- Human - Veterinary

Sterile Formulations

- Solutions, Suspensions, Emulsions, Gels for injection, Implants and External applications
- Parenteral - Oncology / General Injectables / Complex Injectables- Liposomes / Microspheres / Hormonal / LVP, Ophthalmic, Nasal, Otic.

MDI (Metered Dosage Inhaler)

- Dry powdered inhaler, Pressurized metered dose inhalers, Nebulizers



SMARTER SOLUTIONS



Sterile Formulations

Sterile formulations manufacturers are looking for strong and effective solutions to compound a wide variety of formulations, which include products administered by injection (IV, IM, IP, SC-SQ, ID, intrathecal, epidural) or via otic, intranasal or ophthalmic routes.

We have decades of experience in developing innovative technologies and smarter solutions for challenging **pyrogen free and sterile formulations**.

Smarter Systems:

- **Manufacturing/ Compounding vessels**
- Holding/ Filtration vessels
- Filtration skids with **Integrity testing**
- **Buffer Vessels for all filling lines**
- CIP systems
- SIP systems
- Neutralisation systems/ Inactivation systems
- **Integrated suites**
- WFI coolers
- Clean steam sampler
- Temperature control units (TCUs)

Sterile formulations compounded in our systems including suspensions and emulsions are delivered to end users in a variety of dosage forms including **Vial, Ampoule, PFS, Cartridge, FFS/ BFS**.



SMARTER SOLUTIONS



Bio-pharma | Vaccines

Bio-pharma and vaccine industries require large investment in time and capital to effectively translate scientific discovery into novel and affordable therapies.

With decades of experience, DDE has become a strategic driver in providing scalable and flexible bioprocess solutions of high quality.

Smarter Systems:

- **In-Situ Fermenters/ Bioreactors**
- Upstream bioprocess vessels for Media /Buffer preparation, Feed hold, Serum Vessels
- Transfer **sterile filtration skids with Integrity testing**
- Downstream processing – Harvest Vessels, Pooling Vessels, Buffer preparation, Purification Vessels
- **TFF/ Cross flow concentration Skids**
- **Blending/ Formulations vessels**
- **Product feed vessels for filling machine**
- Integrated suites
- Virus inactivation systems
- **Bio-kill/ Decontamination systems - Continuous & Batch**
- CIP systems – Mobile/ Centralized
- SIP systems – Integrated/ Standalone
- Temperature control units (TCUs)

Emergence of new diseases is constantly pushing bio-pharma and vaccine industries to innovate novel therapies and drugs. DDE provides sophisticated and smarter ecosystems to help overcome these challenges.



SMARTER SOLUTIONS



MDI / DPI

There has been a significant rise in the prevalence of diseases that are related to the respiratory system such as chronic obstructive pulmonary diseases, asthma, chronic respiratory diseases and others.

The demand for the metered dose inhalers, Dry powder inhalation and nebulizers has increased.

We have vast years of experience in designing and executing standalone and integrated process systems from Pilot to production scale with **Vibro Mixers, Top mounted Agitators and Bottom mounted Magnetic Mixers.**

Smarter Systems:

- Mixing/ Compounding Vessel
- Homogenizing Vessel
- API charging ball/ Drug addition vessel
- Integrated suite
- Inbuilt or Standalone CIP system



EXPERTISE



Bio-Pharma | Vaccine | Sterile Formulations | MDI - DPI

Our sterile systems are designed to be 100% cleanable and free from dead-leg areas. To ensure that our products offer consistent quality, we use high precision components integrated with a fully automated and intelligent control system and a full cGMP documentation package.

Codes, Guidelines and Standards

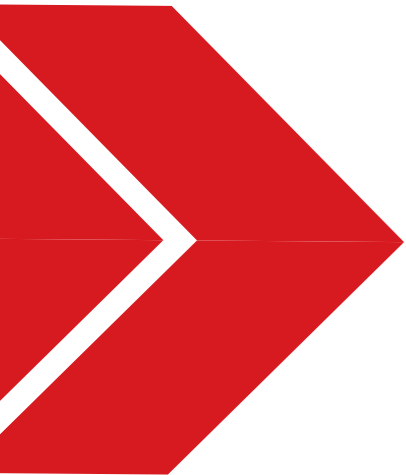
- ASME BPE
- ASME/PED
- GAMP
- cGMP
- FDA, MHRA, WHO
- ASME U-Stamp
- 21CFR Part 11 compliance
- UL
- EHEDG
- CE
- ATEX/ IECEx/ EXd/ EXi/ Exe/ FLP

Smart Design

- PFD and P & ID development
- QbD
- 3D Modelling
- Plant equipment layouts
- AR, VR, MR
- Ergonomics
- LEAN and LEED customized design
- Flexible and Modular
- Focused pharma engineering



SMARTER SYSTEMS





Smart Project Execution

- Single point project manager who manages your project from design to delivery.
- Project & process engineers are dedicated to implementing the strictest international regulatory requirements.
- Highest market expectations met by providing performance guarantee.
- Ensurance of your projects being managed **within budget, on time and meeting your exact deliverables.**



Smart Facilities

- Dedicated FAT centre **with testing bays** which are fully equipped with clean and black utilities
- Static & Dynamic testing of all skids
- Fully equipped with instruments and testing equipments to simulate the conditions at the customer's site
- All skids are fully tested and qualified
- All pre-FAT reports are available for customers prior to FAT visit



Smart Installation

- Installation team consisting of process specialists, automation specialists, technicians, orbital welders and engineers
- Highly experienced Process Engineers ensuring quick start-up
- Fully tested skids reassembled at site with **Plug n Play design**
- Project management systems combined with our **strong on-site management capabilities** ensure the proper control of schedule and costs as well as quality of the field installation work.
- Our engineers also partner with the customer's teams to perform all SAT activities upto OQ
- A well-planned, documented and managed engineering approach is used resulting in a safe and functional environment to meet established design requirements and stakeholder's expectations.



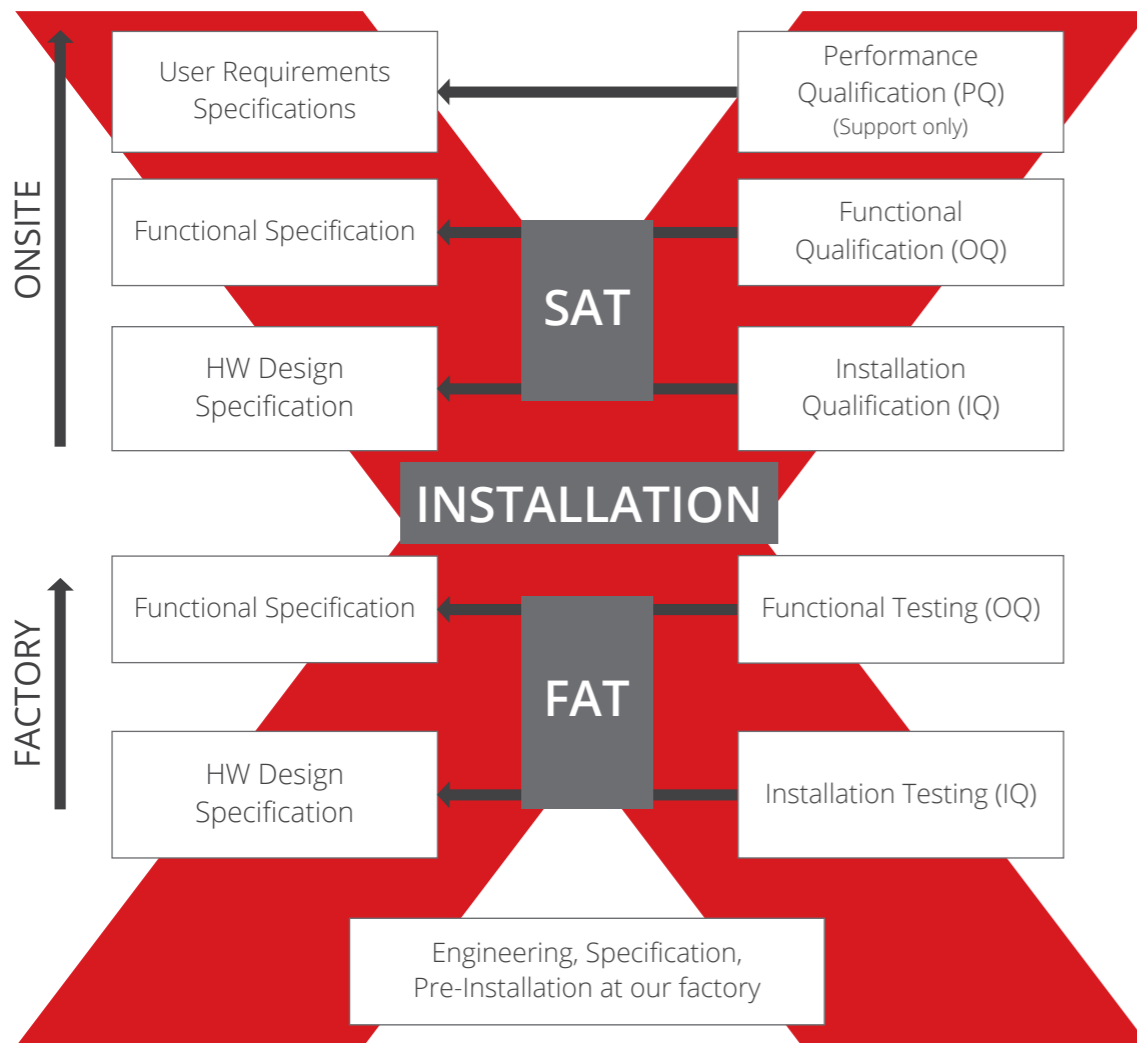
Smart Qualification

- We use a qualification documentation system to monitor commissioning tests (FAT-SAT), optimize non-conformity management, facilitate and speed up reporting processes (review workflow, protocol approval, reports), standardize test protocols
- Qualification is usually carried out by conducting the following activities, individually or combined
- **Design Qualification (DQ)**
The tests and verification required to be undertaken during commissioning is documented in 'Equipment Qualification Plan' (EQP), which is approved by the end user prior to initiation of IQ & OQ activities.
- **Installation Qualification (IQ)**
Documented verification that the equipment or systems are installed or modified
- **Operational Qualification (OQ)**
Documented verification that the equipment or systems perform as intended throughout the anticipated operating ranges (an interactive SOP, comes with the IQ/OQ protocol and on completing the requirements specified in the SOP the IQ/OQ protocol is completed)
- **Performance Qualification (PQ)**
Experienced Commissioning and Performance Qualification (PQ) team has the required technical skills and qualification experience for successful handing over to the customer to start Performance Qualification activities (PQ)

X - MODEL



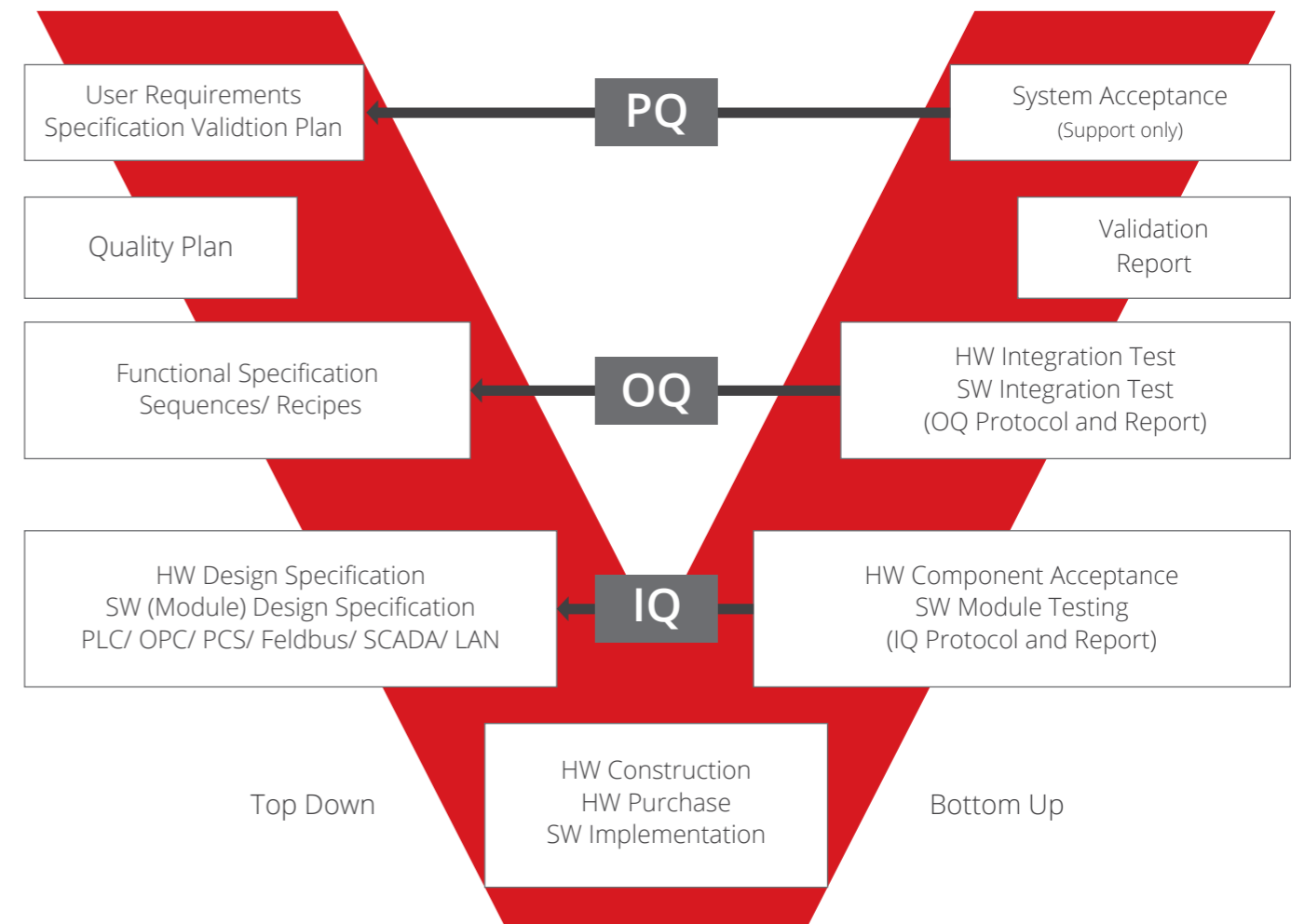
ENGINEERING & AUTOMATION
VALIDATION



V - MODEL



ENGINEERING & AUTOMATION
VALIDATION

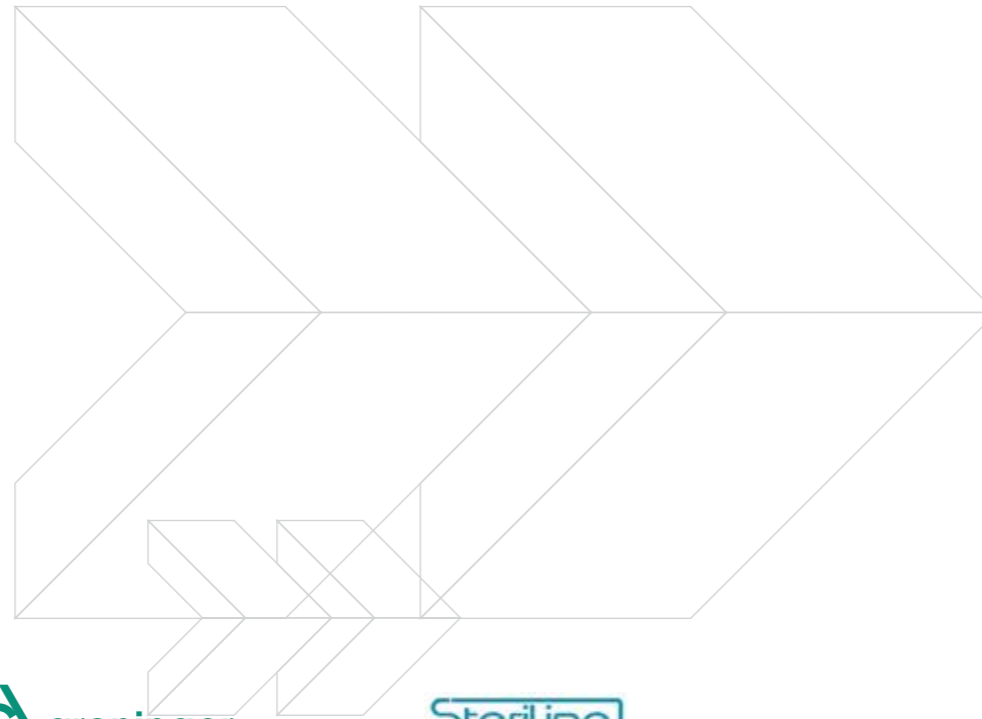


SMARTER SOLUTIONS



Smart Integration Services

- Integration of **different process systems** and package units
- Multifaceted, integrated automation with OEM systems
- **Cross-platform capabilities**
- Integrated user security
- Data collection to meet regulatory and internal requirements
- Plant-wide future-proof automation
- **CIP /SIP/ Process Integration with various OEM's Process systems**
- Handshaking with Controllers of OEM's process systems
- Control system audits
- Some of the process system OEMs integrated by us include



Smart After Sales and Service Support

- Quick telephonic support
- Safe remote access in compliance with 21 CFR part 11
- Maintenance contract for reliable and cost effective plant planning
- Pre-arranged maintenance visits ensuring Zero downtime
- Recommended spares
- Emergency spares replacement
- Software upgradation
- Process and instrumentation support
- System modifications, extensions, improvements
- Onsite and Online services

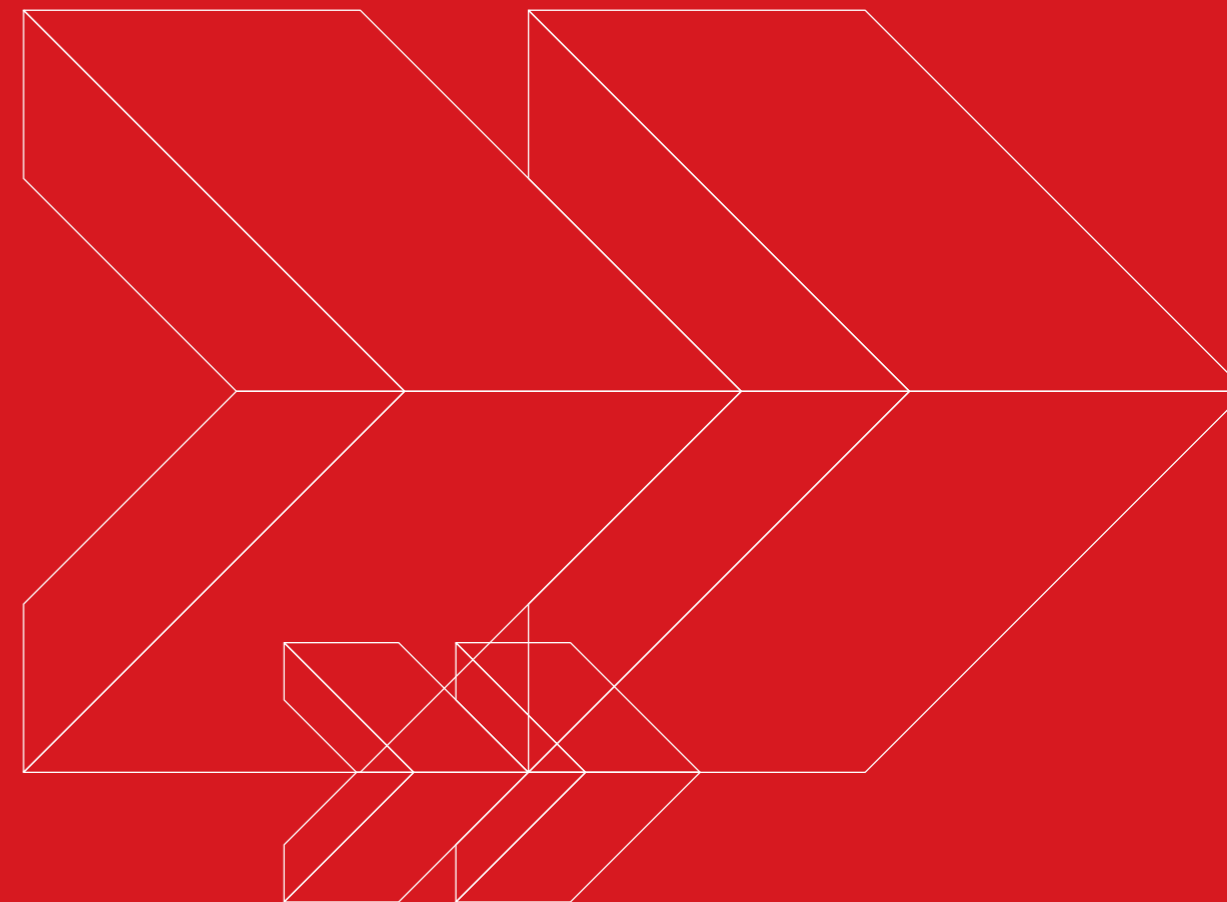
BUILDING RELATIONSHIPS WORLDWIDE



Our systems are prefabricated with modular designs which can be installed quickly in worldwide locations.

We have the ability to assist your company's worldwide expansion and look forward to strengthen and build relationships for a smarter future.

Together we can achieve growth and profitability.





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