

pharma

machines & technology

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bimonthly update on quality movement ...

AUTOMATION IN INDIAN PHARMA INDUSTRY

Analysing Success vs Failures

FUNGI IN CLEANROOMS:

Types, Origins, and Decontamination Strategies

TRACK & TRACE SYSTEMS IMPLEMENTATION IN PHARMACEUTICAL PACKAGING

A Major Challenge

CLEARPACK
EXCLUSIVE



Packaging Automation
PARTNER FOR PHARMA

EXCLUSIVE
INTERVIEW WITH
Govind Bhandari
CEO of Clearpack Group



CLEARPACK EXCLUSIVE



Packaging Automation PARTNER FOR PHARMA

To be in the business, one needs to continuously innovate by responding to market demand. This has been Clearpack strategy from the beginning, adapting to market needs by implementing latest technological development with continuous engagement with its suppliers. Today, Clearpack supplies very high-speed, fully automatic packaging lines from primary filling all the way to end-of-line packaging including serialization & palletizing, and is always prepared for tomorrow's challenge. That, it believes, is the only way to grow with the time.

Read the **CLEARPACK EXCLUSIVE** in the following pages...



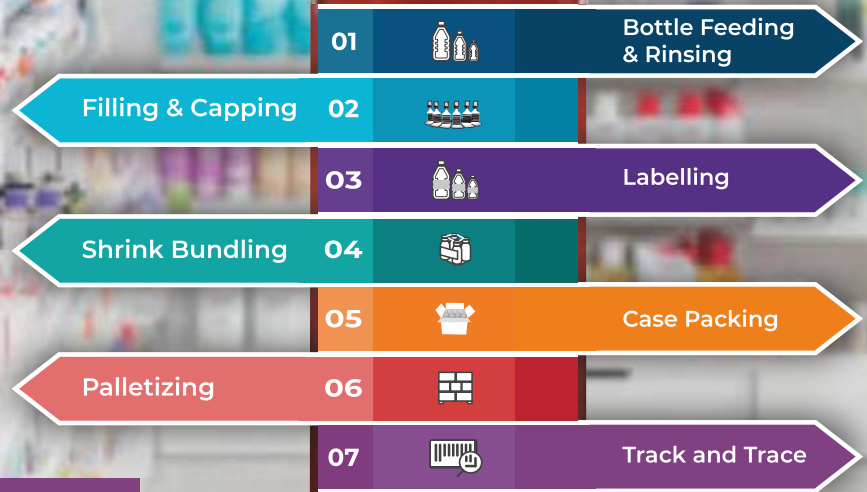
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The Clear

Choice for Packaging

Automation

Safe, Hygienic, And Cost-effective Packaging Automation Solutions for Pharmaceutical Industry

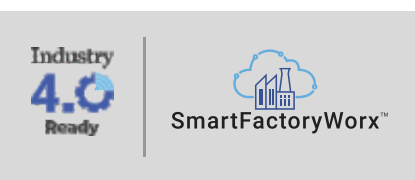


✓ Single Source Responsibility

✓ Packaging Machines For Rigid Containers & Flexible Packs

✓ Can Integrate with Vision System

✓ Efficiency Improvement Solutions



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Packaging automation has become lean, smart, data oriented and driven by AI

Setup in 1994 in India with a dream to build a great packaging automation company, Clearpack is currently a 500+ people strong, stable, and well-organized group with network of offices, R&D and production facilities and a dedicated team of packaging professionals across Southeast Asia, India, China, Middle East, Americas and Europe.

GOVIND BHANDARI

CEO of Clearpack Group

a passionate engineer with incredible energy and insatiable ambition speaks to Pharma Machines & Technology in an exclusive interview.





Q. What has been the nature of technological developments in packaging automation in the last thirty years of Clearpack?

A. Over the last thirty years, packaging automation has become lean, smart, data oriented and driven by AI. I still remember the solutions that were very complex in the early days when we were building machines and now everybody can easily make them. So, it's great that we've moved up in the value chain and welcomed the technology, which can provide more complex solutions.

Q. What has been your role and contribution to packaging automation in all these years?

A. Packaging automation is core of our business. We started in this domain 30 years ago when packaging automation was not high on agenda for many companies.

Our role has been to help our customers identify bottlenecks in their packaging lines, suggest optimum automation solutions to overcome the same and prioritise implementation of these solutions.

In terms of contribution, we have always remained mindful of affordability and ROI for our customers, incorporated latest technologies in our solutions and use non-proprietary standard OEM components to ensure that our customers always have access to parts from multiple sources.

Our solutions are designed in Europe (Italy) by our partner companies and we build, assemble and test these machines in our factories in Greater Noida, India and Kuala Lumpur, Malaysia under their supervision to ensure same performance level and reliability, while keeping solutions affordable.

Last but not the least, we have built well trained teams of service technicians and engineers in all the markets we operate in to be able to support the solutions we supply and train our users.

“ To be in the business, we need to continuously innovate by responding to market demand. This has been Clearpack strategy from beginning. This also opens new market and less competition. Clearpack has been leading this upgradation from front. We adapt to market need by implementing latest technological development with continuous engagement with our suppliers. We always keep our door open for new concepts/ designs and at any given time we would be working on an average 20 percent on such projects.

Q. Why and how Clearpack is the clear choice for packaging automation?

A. With our vast industry experience, we provide affordable solution for our customers based on line-speed, available workspace, product shape, size and future requirement. Clearpack works as a single source supplier with proven expertise to design, integrate and install complete packaging lines leading to high efficiency, cost and time saving. These world class machines are now made in India and backed by strong network of experienced service engineers. All the critical spares are available at our factory to serve and deliver the spares in fastest timeline to ensure minimum downtime and low maintenance cost.

“ Today, we supply very high-speed, fully automatic packaging lines from primary filling all the way to end-of-line palletizing to the top consumer companies in the world. Our decision to acquire and start factories in Europe, especially in Switzerland and Italy, was very important because we are seeing the flywheel effect now – even though it took a lot of hard work to get started, it takes much less effort to keep it moving.”





Q. The pandemic has changed the world a lot in the last two years, how challenging has it been for Clearpack and how did you take on it?

A. The pandemic has disrupted business on many fronts. Nevertheless, Clearpack resumed its operations following the local authorized guidelines and protocols. Our field-service teams have been working on-site, or remotely, to support the market. We tried to minimize service disruptions to our clients and worked hard to give them packaging automation solutions to assist manufacturers keep their workers socially distanced more safely on the factory floor without hampering overall productions.

Q. What are the safe, hygienic, and cost effective packaging automation solutions you offer to pharma industry?

A. Our solutions can be broadly categorised into Primary Packaging (like Filling, Capping, Sachet machines) and End-of-Line Packaging (like Shrink bundling, Case packing, Palletizing machines). Our solutions conform to the necessary ISO and EN standards and documentation to meet the safety and hygienic standards, and where necessary regulatory requirements specified by our customers.

Q. How different is catering to pharmaceutical industry compared to consumer-packaged goods (CPG)?

A. We all know that the primary objective of consumer packaging is to protect the contents from microbiological, chemical, physical, and atmospheric contamination and preserve the contents and thereby protect consumer's health. Packaging is essential and critical for promoting food safety, extended shelf-life and thereby enhancing food security.

The quality of the packaging of pharmaceutical products plays a very important role in the quality of such products. It must protect against all adverse external influences that can alter the properties of the product, e.g., moisture, light, oxygen, and temperature variations, and therefore the packaging components so used need to protect at each stage:

- Protect against biological contamination, protect against physical damage.
- Carry the correct information and identification of the product.
- The kind of packaging and the materials used must be chosen in such a way that the packaging itself does not have an adverse effect on the product (e.g., through chemical reactions, leaching of packaging materials or absorption).
- The product does not have an adverse effect on the packaging, changing its properties or affecting its protective function.

The resulting requirements must be met throughout the whole of the intended shelf-life of the product.

“

We've partnered with suppliers who understand our requirements very well and have built very close relationships with them. Clearpack doesn't like to make anything that can be done by other companies more efficiently or better. We concentrate on what we do best and outsource whatever else can be done more competitively by our partners, so that we can provide optimum solutions to our customers.”

“

Packaging development has become an integral part of pharmaceutical drug development and manufacturing. The pandemic, COVID-19 has further strengthened the collaboration between the pharmaceutical industry, packaging technology suppliers, and regulatory authorities, creating a solid network for speed and efficiency in development and supply of safe and effective medicines in the future.





Q. Is pharma industry lagging behind other high-risk industries in terms of innovation? What are your comments?

A. The pharma industry has been under a constant pressure to provide packaging components which are inert in nature. In other words, that do not have any reactions whatsoever with the medicine over the entire shelf life of the drug substance and beyond. All this can be achieved through the long term and accelerated stability studies that are a part of the drug substance development and release, etc.

Packaging development has become an integral part of pharmaceutical drug development and manufacturing. The pandemic, COVID-19 has further strengthened the collaboration between the pharmaceutical industry, packaging technology suppliers, and regulatory authorities, creating a solid network for speed and efficiency in development and supply of safe and effective medicines in the future.

In my opinion, it would be an error to say that the pharma industry is lagging behind. Of course, in some areas like injectable dosage forms where the interacting packaging components that come in direct contact with the drug substance and have immense importance over the other dosage forms. All those need to be selected based on the extensive stability studies of being inert in terms of chemical reactivity of the interacting surfaces.



We have been supplying packaging machines for close to three decades. Now, in addition, we have smartfactoryworx system to monitor the line performance of existing or new production lines and to improve over-all line equipment effectiveness (OEE) while reducing maintenance costs by predicting and avoiding breakdowns. The solution includes invisible supervision on each machine, recording bottlenecks of production lines, automatic alerts, and more. Real-time data is generated for the improvement of the efficiency of the production lines. This has helped many of our customers to improve their OEE and reduce production downtime."

Q. Minimizing rejects is a major challenge in pharmaceutical packaging. How are you addressing this issue?

A. Rejection is a major challenge for any industry including pharma. Rejections could be due to quality issues in packaging materials or with machine related issues. Clearpack is working with our customers to understand the limitation from packaging materials and designing the machine which can work within max input quality deviation. In addition to this, Clearpack is constantly engaged in research and innovations to improve the machine performance adopting to latest technologies. We have also prepared our machine for industry 4.0 and offer a performance monitoring solution to identify the areas leading to maximum rejects.

Q. Speed gets faster and faster, and technology is constantly changing, it is extremely challenging to be in the business of packaging automation. What has been the Clearpack strategy?

A. To be in the business, we need to continuously innovate by responding to market demand. This has been Clearpack strategy from beginning. This also opens new market and less competition. Clearpack has been leading this upgradation from front. We adapt to market need by implementing latest technological development with continuous engagement with our suppliers. We always keep our door open for new concepts/designs, and at any given time we would be working on an average 20 percent on such projects.

Q. How important and effective are building partnerships and acquisitions in your kind of business?

A. Today, we supply very high-speed, fully automatic packaging lines from primary filling all the way to end-of-line palletizing to the top consumer companies in the world. Our decision to acquire and start factories in Europe, especially in Switzerland and Italy, was very important because we are seeing the flywheel effect now – even though it took a lot of hard work to get started, it takes much less effort to keep it moving.





We've partnered with suppliers who understand our requirements very well and have built very close relationships with them. Clearpack doesn't like to make anything that can be done by other companies more efficiently or better. We concentrate on what we do best and outsource whatever else can be done more competitively by our partners, so that we can provide optimum solutions to our customers.

Q. Brief about your Industry 4.0 readiness, and your SmartFactoryWorx?

A. Clearpack is industry 4.0 ready. We have been supplying packaging machines for close to three decades. Now, in addition, we have smartfactoryworx system to monitor the line performance of existing or new production lines and to improve over-all line equipment effectiveness (OEE) while reducing maintenance costs by predicting and avoiding breakdowns. The solution includes invisible supervision on each machine, recording bottlenecks of production lines, automatic alerts, and more. Real-time data is generated for the improvement of the efficiency of the production lines. This has helped many of our customers to improve their OEE and reduce production downtime.

Q. What does it mean for your company to be named one of the top 50 SMEs in the E50 Awards this year, especially amidst the challenges of Covid-19?

A. It is a great honor to be awarded as one of the top 50 SME's in Singapore in such a challenging year, especially as we enter our 30th year of being in the industry this year. We view this as a recognition of our agility to be able to change our approach to the market quickly despite challenges faced last year. It is also a recognition of our team members across the region who work tirelessly to ensure customer delight.



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Complete Primary Packaging Solution for Pharma Industry

The quality of the primary packaging of pharmaceutical products plays a very important role in the quality and shelf life of final product packs. It must protect content against all adverse external influences that can alter the properties of the product, e.g., moisture, light, oxygen and temperature variations, biological contamination etc. Commitment to good manufacturing practices (GMP) compliance as required by pharma industry is the topmost priority of Clearpack. Here is a glimpse of popular solutions:

Rinsing Machines

TORQ Range of Rotary Rinser meets the 21 CFR part 11 compliance by pharmaceutical industries and provides required cleaning for the interior of the containers in medicines production lines before for the next step of liquid filling.

TORQ range of Rinser machines can have multiple cleaning treatments, like blowing with clean air, blowing with ionized air, vacuum suction, cleaning with water / cleaning solutions.





Salient Features:

- Suitable for Glass / PET / HDPE Bottles of different shapes & sizes
- Compact Design in SS304 construction with safety interlock
- Multiple Treatments possible for bottle cleaning - Air Blowing, Suction, Liquid Rinsing
- Dive in nozzle option available
- Star wheels provided with clutch mechanism
- Drainable machine frame - ease of cleaning
- Bottles to be loaded on conveyor, complete rinsing operation is automatic
- Used water can be recycled if needed
- Motorized Turret up/down movement
- Machine comprised with Conveyor motor and Main motor - both with AC Drives
- Operator friendly Customized HMI touch screen
- No bottle no Liquid discharge
- Various models designed to cover production range from 50 bpm to 600 bpm.



Rinsing Mechanism:

- **Rinsing with Air Blowing Treatment:** The Rinsing is equipped with Compressed Air Filtering system composed of Oil removing filtration degree of 0.6 μm . As well as final filter equipped with filtration degree of 0,003 μm (air or gas).
- **Rinsing with Suction Treatment:** Each nozzle is surrounded by a slight vacuum chamber (suction cup) and is positioned, during the blowing phase, close to the bottle mouth. These cups relate to a central rotating manifold by a timing ring. During the working cycle, a side channel exhaust fan removes contaminants and air from the bottles by vacuum.
- **Rinsing equipped with Air Ionizing treatment:** Each nozzle is equipped with a high-tension ionizer (8 kV) and blows ionized air inside the bottles. Ionized air blown into bottles allows the detachment of the dust particles from the inner surface of the bottles. The supply includes the AC high voltage (8 kV) feeder. The ionization device is controlled from the operator panel.
- **Rinsing equipped with Water Rinsing treatment:** It is possible to provide a recovery tank that can be used for recirculating the liquid for cleaning purpose.

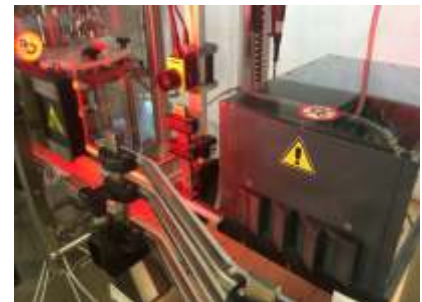




Linear Flow Meter Filling Machine

The LFM series of filling machines are inline intermittent machines equipped with flow meter technology (volumetric measuring principle). For the liquids that are conductive, Magnetic Flow Meters

are employed for each nozzle. For liquids that are non-conductive, Mass Flow Meters are used for each nozzle. Both the Magnetic and Mass Flow Meters are applied for measuring the liquid with recipe-based control system (from HMI) for accurate and repeatable filling of both large and small volumes.



Soft/Multi-Push Reject



Capping Solution for Pharma Industry

TORQ provides a complete range of Capping solutions starting from linear Single Head Servo Capper for low speeds to Rotary Cappers with 3 to 20 capping heads. The machines are capable of handling Glass, PET, HDPE all kind of bottles for speed ranging from 15 to 400 bpm.

TORQ capping machines are suitable for handling all types of closing applications; press-on Caps, Aluminium screw, CRC Caps, Pre-threaded, oriented, dispenser, pump, and triggers.

Salient Features:

- Various model ranging from 5 nozzles to 14 nozzles in a single frame
- To cater for Glass, PET, HDPE bottles for production speed up to 200 bpm
- Bottle transfer by Servo driven timing screw
- Nozzle Up/Down movement by Servo motor
- Foamy liquids handled by Servo Driven Dive-in Nozzles
- Liquid circuit supplied with gravity or pressurized tank (product dependent)
- Hygienic non-contact filling
- The liquid circuit is comprised with Automatic CIP function
- Soft-push Rejection System to reject bottles that are out of fill volume tolerance
- The machine is designed considering CIP operation to be carried out from HMI
- State-of-the-art HMI with internal diagnostic & alarms
- Monobloc execution of Filler with Single Head Capper is possible for lower speeds





Depending on the type of Cap, the machine can be equipped with special capping heads:

- ROPP caps Chuck with thread forming and crimping wheels
- For Screw Caps Machine comes with standard Magnetic clutches for normal torque range or with Hysteresis clutch (washable execution) with high torque accuracy
- Pressure head with axial spring (different measures) to apply the correct vertical load
- Positive gripper chuck with mobile grippers controlled by a cam, for shaped caps
- Special chucks with vacuum or with grippers

Salient Features:

- SS Construction HMI panel designed for easy Operator Interface with display of SKU, alarms history and production data.
- Capping heads rotation speed controlled by induction or brushless motors.
- Orientation of Caps with respect to Bottle front / back face is by Vision Camera & Servo Motor
- Remote assistance with Ethernet connection / Vision Camera for checking the correctness of capping
- Quick change over and automatic regulation with recipes
- TORQ machines are customized according to the pharma requirements always ensuring construction quality of the highest level
- Product contact parts in AISI304 with AISI316l option
- IES (Inox External Surfaces) and Washable execution machines are available

Clearpack manufactures Torq Rinsing, Filling & Capping Machines in India under license manufacturing





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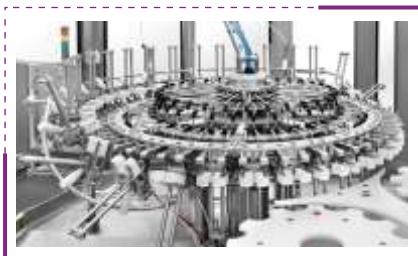
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Efficiency

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Technology

Primary Packaging Machines for Rigid Containers and Flexible Packs.



Our Solutions

 Bottle Unscramblers

 Bottle Rinsers

 Filling and Capping

 Labelling Machines

 Form Fill Seal Machines



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Always prepared for newest challenges

In an exclusive interview

PIYUSH BHANDARI

Area Sales Head - Clearpack speaks to Pharma Machines & Technology on the challenges in building automation solutions for pharma industry, how Clearpack keeps a close watch on the market and consumer behaviour and prepare itself for the new challenges, and on the newest solutions Clearpack offers to pharma industry.



Q. What are the challenges in building automation solutions for pharma industry, compared to CPG?

A. For pharma, a great level of attention and detail must be on hygienic design, material selection, validation, documentation, and control as compared to CPG. I must add that many CPG products also demand high hygienic design, so we are quite familiar with these requirements.

Q. The fast-changing pharmaceutical industry calls for newest packaging solutions. Is the packaging industry equipped? What are your comments?

A. At Clearpack, we keep a close watch on the market and consumer behaviour and prepare ourselves for the new challenges. Pharmaceutical industry demands innovative automation solution given the nature of the product and added by tough regulatory requirements. These requirements keep changing based on the country where these products are exported and hence the solutions that we provide should be extremely flexible and easy to adapt to change with minimum cost implication. Clearpack is always prepared for tomorrow's challenge, and we believe this is the only way to grow with the time.

Q. Investing in the right technologies has become an integral part of pharma industry's efforts to prepare for the future. How do you help the industry out?

A. Innovation is the key here. They can be either driven by our customer or by the technology provider like us. We closely work





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In recent years, we have seen exponential growth in automation adoption and expanded our factory in 2016 in India. Last year, amidst COVID lockdown, the company saw further growth potential in India and accelerated its expansion plans to support the increasing production demand. We also established our sister concern Smart Factory Solutions Pvt Ltd to offer Efficiency Improvement Solutions – a must have tool to monitor and improve overall productivity of production lines.”

with our customer in developing a solution from concept. In many cases these investments may not lead to an immediate business, but Clearpack consciously spends time and resource in these developmental works as we believe this is the road map for innovations and thereby, we can prepare the industry for future.

Q. It is said that the growth rate of technology has been much faster than the overall growth of pharma industry. What are your comments?

A. The trends in technology development have indeed taken enviable strides over the overall growth. But this has been fast tracked by the pandemic and the technology has been close behind to address the requirement of providing the vaccine in a record time of 15 months bringing it down from 5 to 8 years or more.

Q. Brief about your offices, factories and people strength globally?

A. Clearpack was setup in 1994 in India with a dream to build a great packaging automation company. We are currently a 500+ people strong, stable, and well-organized group with network of offices, R&D and production facilities and a dedicated team of packaging professionals across Southeast Asia, India, China, Middle East, Americas, and Europe.

In recent years, we have seen exponential growth in automation adoption and expanded our factory in 2016 in India. Last year, amidst COVID lockdown, the company saw further growth potential in India and accelerated its expansion plans to support the increasing production demand. We also established our sister concern Smart Factory Solutions Pvt Ltd to offer Efficiency Improvement Solutions – a must have tool to monitor and improve overall productivity of production lines.

Q. What are the newest solutions you offer to pharma industry?

A. We have developed new solutions and models in both Primary Packaging and End-of-Line space.

In Primary Packaging, from pharma standpoint, our new solutions are Linear Filling technology using Flow meters with full CIP capability, Hygienic nozzle, and high filling accuracy (0.3%), Net weight Rotary Filling machines and Servo cappers with full Torque control.

In End-of-Line space for bundling and case packing, we have developed several new and compact solutions around Vision and Robotics integrated with Track and Trace. These solutions have high degree of flexibility with quick changeover for formats. These could be particularly interesting for pharma sector.



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Automatic

Shrink Packaging

Solutions

Versatile range for machines for use with polyolefin/ LDPE film and for individual or multipacks.



Why Choose Us

-  Single Source Responsibility
-  Vast Experience
-  Make in India
-  Service & Spares Support
-  Industry 4.0 Ready



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Need of Robotics Automation in End of Line Packaging



Industrialization of consumer goods companies are moving into next phase of automation in the form of End of line automation. Increased throughput, labor shortage, quality and consumer complaints, supply chain automation demand are the few important factors pushing this automation.

One of the key factors pushing end of line automation in most of the industry is need for boosting efficiency and there by output. This is a key factor driving the end-of-line packaging market. While new production lines are being set up, there is also great need to automate existing low to medium speed lines. Customer desire to modernize the manufacturing plants will benefit the market in general and the technology provider in specific.

While calculating the return on investment for automation, it is very important to know the total cost of ownership (TCO) of the equipment. This is as important as the initial automation acquisition cost as this is recurring cost over the period of equipment lifetime. TCO should consider utilities, labor costs, spare and service cost spread along the length of the life cycle. Any robotic automation for end of line gives excellent benefit in terms of TCO due to its low spare part and maintenance cost due to time tested robots which have very high MTBF records.

Robotic automations are deployable with some modification to do a totally new task. This gives high flexibility and low redundancy factor.

Clearpack has been working with leading companies in the region in developing various robotic based applications.

Primary Packaging	Bottle Unscrambling Depalletizing Bottle Feeding	Pick & Place Tray Loading & Unloading
End of Line Packaging	Carton loading Case packing	Case sealing Palletizing





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Single Source Responsibility For Your Packaging Lines

Tablet Bottle Line Automation with Track and Trace

Pharma companies often face problem with space for end of line equipments. In addition to length and width of the area, roof height also a concern in many companies.

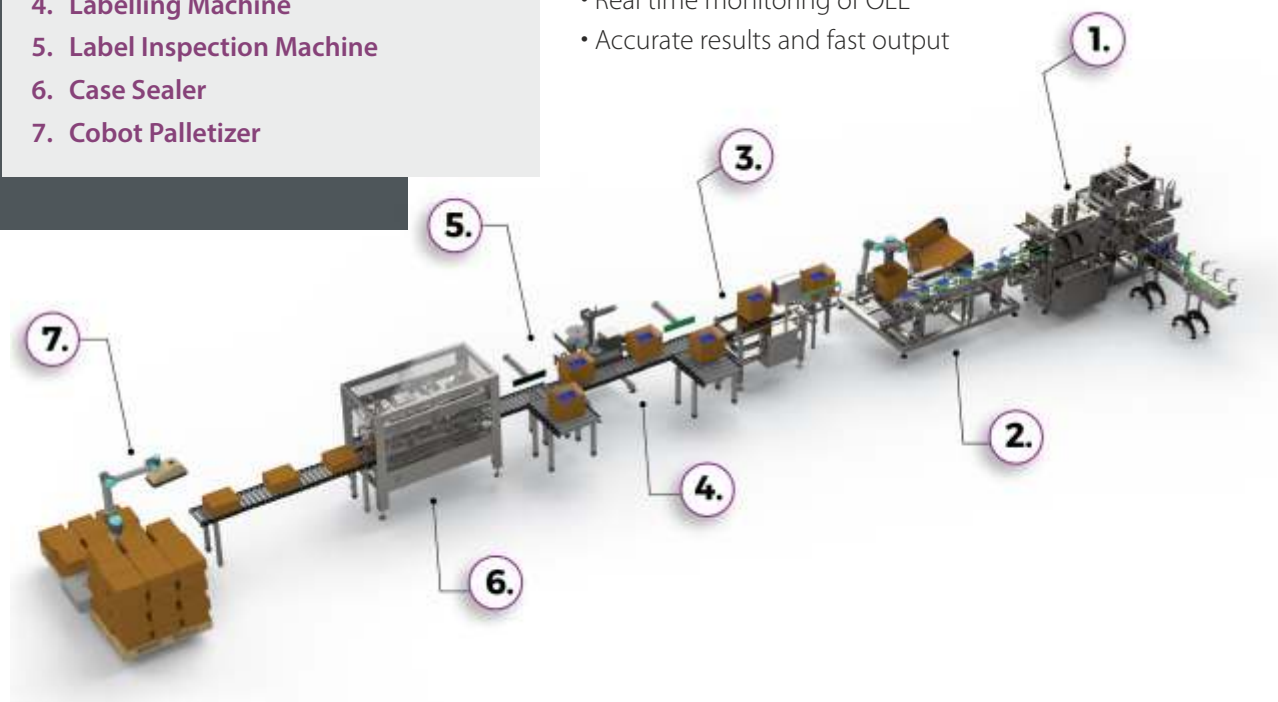
1. Automatic lane division /collation system with Shrink bundling
2. Cobot case erector and packer
3. Check weigher and Rejector
4. Labelling Machine
5. Label Inspection Machine
6. Case Sealer
7. Cobot Palletizer

One of the leading pharma company in India had similar problem. But this was not a deterrent for them to completely automate their end of line operation. They also had to include product serialization and aggregation.

Clearpack came up with a unique solution which can very well fit in the space provided. Solutions were based on robotics which helped optimize the footprint of the equipment. Clearpack jointly worked with a leading track and trace solution provider to put in place a complete line, taking care of all critical interface points between different partners of the project. This helped customer getting a completely engineered and tested solution from a single source without worrying about integration.

Benefits to customer:

- Fully automated solution with no manual intervention
- 100 % Track and Traceability integration to the manufacturing process and visibility in the entire supply chain
- Overcoming challenges of unstable bottles after application of PIL (Patient Information Leaflet)
- Collaborative operation
- Easy integration with the existing line
- Low operating costs
- Safe & hygienic packing
- Faster ROI
- Small Footprint
- Flexible and durability of machinery for long run
- Real time monitoring of OEE
- Accurate results and fast output





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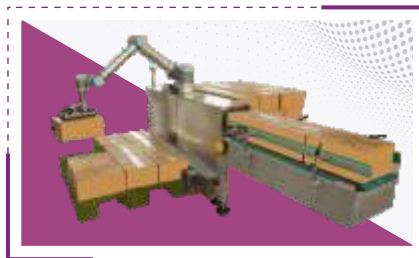
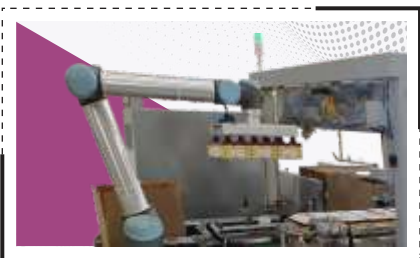
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Packaging Applications

Using Cobot

Case Erecting, Case Packing & Palletizing



Features

-  Flexible Deployment
-  Collaborative Operation
-  Easy to Install
-  User Friendly
-  Cost Effective

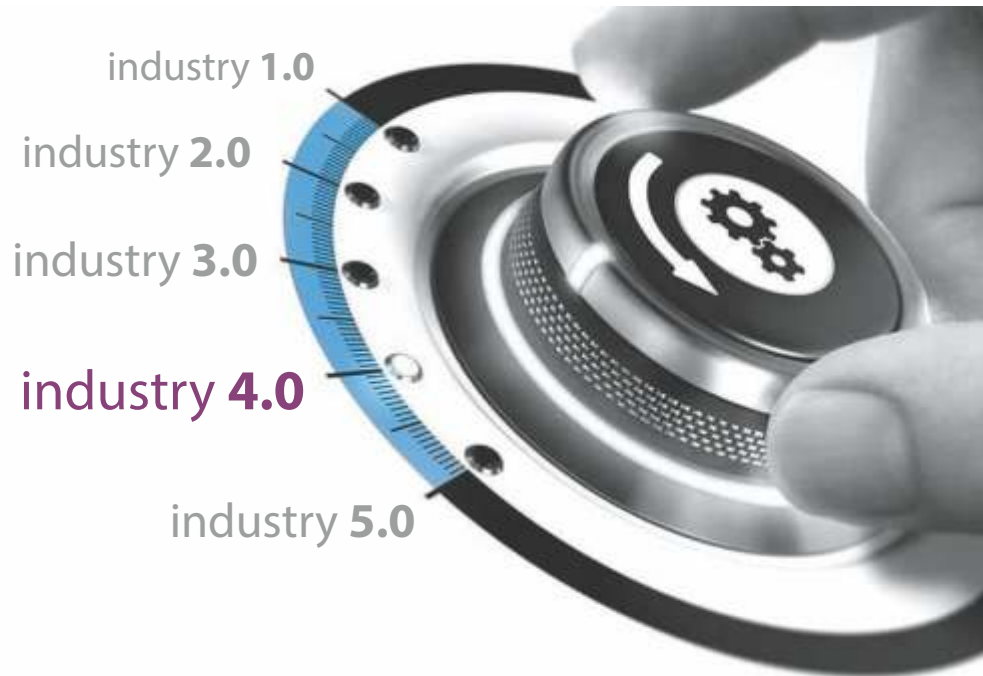


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What gets measured, gets improved using IoT and i4.0

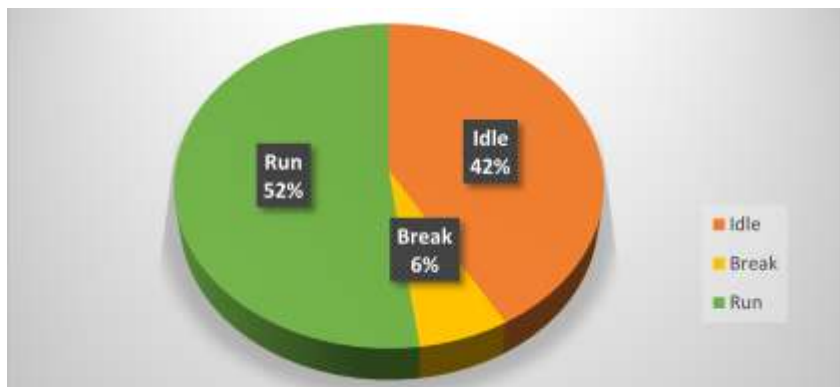
With IoT and i4.0 there is no excuse now not to digitize the machine in real time and improve labour productivity, asset monitoring, % yield of the material, and environment.



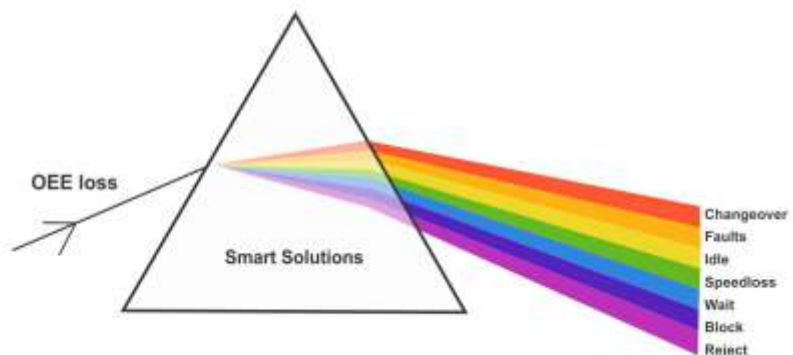
Digitizing machine, Clearpack provides:

1. Line loss analysis
2. Yield of the material used
3. Labour productivity

A typical 8-hour shift will it look as below with OEE of 56%



Helps to get breakdown of the idle time as below:





All the dashboards and reports are action driven:



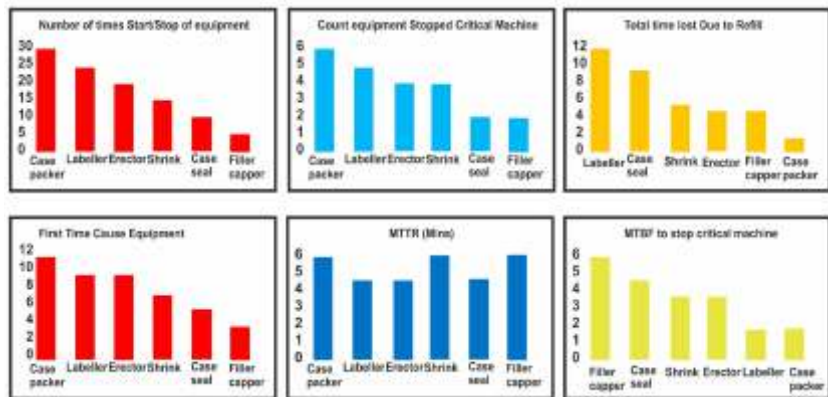
Some of the important stoppages that are most detrimental to OEE are:

1. Minor stoppages
2. Changeover time

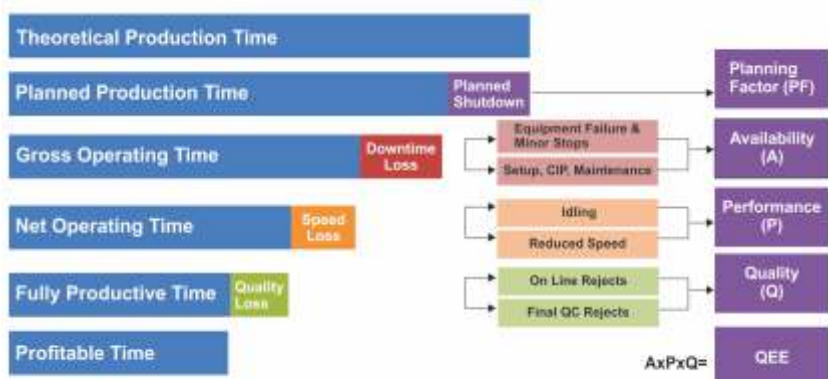
Clearpack will provide:

1. Continuous monitoring of OEE
2. Stoppages alerts

Report:



The OEE analysis is based on DIN 8743



Each month there is performance improvement summary. This will give what action needs to be taken, and where there has been improvement.

With IoT and i4.0 there is no excuse now not to digitize the machine in real time and improve:

- Labour productivity – Reject / rework
- Asset monitoring
- % Yield of the material
- Environment

With ROI of less than 2 months, would you not try one of the lines? Reach Clearpack today.