Indian Pharmaceutical Industry has been a global powerhouse for supply of affordable medicines. Leveraging on low labor cost and advanced R&D capabilities, India supplies over 20 percent of global generics medicine volumes. Indian industry is also at the forefront of bringing biosimilars to the global population.

The last 3-5 years have seen the industry focused on strengthening quality systems and building stronger compliance in the endeavor to provide high-quality low-cost medicines. In this journey, however, the industry has lagged in leveraging power of the digital revolution to enhance productivity and optimization. Often, more people have been deployed in order to address operational problems, leading to low productivity.

COVID-19 has given an impetus to the much-awaited digital transformation journey in operations. During the COVID pandemic, the industry faced unprecedented challenges—with severe lack of manpower and lack of infrastructure supporting remote operations. Lack of consolidated managerial data brought the management to pull together make-shift solutions to support informed decision making.

The industry has taken multiple short-term measures to mitigate impact of COVID-19 on manufacturing operations. These included redesign of shifts, deployment structures, basic systems for remote work, and enhanced coordination with suppliers and logistics partners for facilitating material movement. Companies also set up a make-shift control room with data flow to enable decision making. The companies that had invested in digitization were able to orchestrate quicker and more efficient response to disruptions.

The Digital Opportunity Ahead
The measures taken during COVID allow companies to rethink their operations structurally. Companies could step back and chart out a transformative journey towards a digitized and integrated manufacturing function, with data available in an
analyzable format to deliver transparent decision making and productivity.

We believe that organizations could think through the Future of Manufacturing along 5 core pillars, as outlined in Exhibit 1 below:

**DATA ACQUISITION AND ANALYTICS**  
The backbone enabling Future of Operations. Key is to capture data in a structured format from the shop floor (both Manufacturing and Quality) and build analysis layers on top towards optimization

**SHOP FLOOR PROCESSES**  
The core driver of impact - simplification, optimization and improvement in the operating processes to achieve higher productivity and outcomes. Data and digital interventions could simplify the operating processes which have become complex with additional layers of checks and balances over last few years. Solutions could eliminate duplication, enable better operating control on parameters and generate higher accuracy

**ASSET PERFORMANCE**  
Like shop floor processes, this is a core operating pillar. Asset productivity and reliability will play a crucial role with opportunity towards mechanization of repeated tasks, improvement in reliability through elimination of minor stops and data driven condition-based optimization, & simulation of potential outcomes

**PEOPLE ORGANIZATION OF THE FUTURE**  
A significant shift in talent and capabilities of the operating team would be critical to traverse the journey. Currently, a large portion of shop floor manpower comprises of semi-skilled operators. With mechanization of tasks, and data based operating controls, we expect to see a shift towards more skilled taskforce, capable of decision-making using analytics. The journey would also require technology skills to build and manage analytics logic & process controls

**CONTROL TOWER**  
The central nerve center for managerial decision-making leveraging data. Availability of data in a digital analyzable manner

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**EXHIBIT 1 | Future of Work Thinking Around 5 Core Operating Pillars for Manufacturing**

Source: Interviews with industry experts, BCG analysis.
would enable decision making for ongoing real time optimization, and move from department level optimization to organization and ecosystem level optimization.

The Journey towards Future of Operations

The journey towards Future of Operations would involve traversing a 4-stage journey. This progression is outlined on a maturity framework in Exhibit 2.

Many of the plants in India are currently operating at Level 1 of maturity in this journey, with initial steps and pilots of Level 2 and 3 capabilities. Given the technology infrastructure required to traverse the journey, older generation plants would aspire towards reaching Level 2 in the short term, and subsequently invest towards Level 3 and 4. The new generation plants could aspire to reach at Level 3 and Level 4 of performance as the up-front goal.

A summary description of the five core pillars along the four levels of maturity is presented in Exhibit 3.

The following section outlines the details of this journey.

**LEVEL 1: ENABLING OPERATIONS CONTINUITY AND DESCRIPTIVE ANALYTICS**

The 1st level in this journey is aimed towards transparency of information and ensuring operations continuity. This would start with building standardized ways of working, measuring performance against the standards and optimizing at a department level. Data transparency across departments would allow better informed decision making (versus individual driven ad-hoc decisions). This level would also see basic remote working infrastructure to support operations continuity in times of disruption. The 5 pillars would shape up as outlined below:

**Data acquisition & analytics**

At Level 1, shop floor data would need to be available in a digital manner, to support decision making. This level is defined by:

**EXHIBIT 2 | 4-Step Journey for Achieving the "Future of Work" in Manufacturing**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Old legacy plants</strong></td>
<td><strong>New plants</strong></td>
<td><strong>Step-jump in capability</strong></td>
<td><strong>Lights out plants</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Org of techno-digital experts to drive close collaboration and optimization across eco-system</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Prescriptive systems and control logic process management</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Real time feedback loops for enhanced outcomes on a continuous basis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality integral part of manufacturing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Predictive analytics and Optimization of integrated outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Data driven decision making using analytics on historical performance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• e2e optimization across departments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Enable operations continuity through transparency and descriptive analytics</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Transparency of performance with localized optimization and smooth information flow</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Multi-skilling to reduce dependence on specific individuals</td>
</tr>
</tbody>
</table>

Source: BCG analysis.
Implementing base digital data acquisition systems such as E-logbooks, LIMS etc.

Building a unified data repository to enable ‘one version’ of truth for the organization

Making data transparently available across departments for decision making and optimization on a real time basis

**Process simplification**

Operations today often struggle with multitude of SOPs, with complex instructions and data entries. While operating SOPs and BOMs are defined, nuances of effective process execution often come with experience and lead to high reliance on individual operators. Level 1 simplification attempts to enable any operator in being efficient in executing the task by:

- Reviewing, refining and simplifying the SOP pyramid
- Simplifying instructions, eliminating subjectivity or ambiguity from the operating process to achieve highest productivity
- Enabling standard work instructions, with tools such as role cards and digital SOPs

This also gives an opportunity for organizations to harmonize processes in the network by leveraging unified work templates

**Asset performance & automation**

Level 1 is characterized by optimization of operating efficiency, by focusing on enhanced asset reliability. This would include:

- Eliminating minor stops and other OEE loss drivers
- Enhancing operating speeds of the equipment by working with OEMs
- Focusing on reliability through trigger or condition-based maintenance (versus traditional preventative maintenance)

At this level, companies should also consider investing in mechanizing the heavily

---

**EXHIBIT 3 | “Future of Work” is a Journey Towards Global Competitiveness**

| Level 4 | Localized optimization of processes with std. work | Localized equipment performance optimization | Operators focus on SOP execution | Gamified multi-skilling | Departmental optimization and localized scheduling |
| Level 3 (Predictive systems) | Control logic driven process operations | Condition based optimization | Operators taking data based decisions | Remote working for support teams | Organization level E2E optimization |
| Level 2 (Integrated Outcomes) | Descriptive data analytics | Harmonized processes across network | Site level E2E optimization | KPIs beyond output (e.g.: energy, sustainability) |
| Level 1 (Operations continuity) | Digital data acquisition | Integration of data, 1 version of truth | Operators handling exceptions | Integrated QC with Manufacturing |

**Data acquisition, analytics**

- Digital data acquisition
- Integration of data, 1 version of truth
- Predictive analytics & synchronous feedback loops
- Control logic driven process operations
- Real time perf. simulations
- Condition based optimization
- Operators handling exceptions
- Operators taking data based decisions
- Remote working for support teams
- Organization level E2E optimization

**Process simplification**

- Reviewing, refining and simplifying the SOP pyramid
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**Source:** Expert discussions, BCG analysis.
manual repetitive tasks through low investment solutions (for example, Hydraulic loading, GMP washer etc.).

**Org of the future**
Simplified processes and standard work would enable significant shift in organizing the workforce. Currently, operators are often deployed on select processes basis their skill and experience. Standardization and enhanced reliance on data would allow productivity increase through:

- Deploying operators on multiple processes through multi-skilling
- Reducing the flex ‘workforce’ requirement in system by efficient utilization of manpower across processes / departments
- Capability building leveraging digital solutions, like digital SOP, enabling faster time to productive deployment

Digital solutions also allow a strong track on deployment linked to training and skillling, further enhancing productivity

**Control tower**
Level 1 control tower would enable companies to optimize decisions basis data at a department level, with transparency of information from across different departments. This optimization would support enhanced resource productivity and reduced time spent towards cross functional debottlenecking

- Optimizing operating schedule for different equipment, with knowledge of upstream bottlenecks
- Performance monitoring on a real time basis, enabling corrective actions
- Supporting remote video enabled shop floor visits—for example, for audit / gemba purposes, and enabling operations continuity in times of disruption

**Level 2: Predictive analytics and optimization of outcomes in an integrated manner**

With the building blocks of shop floor data systems & processes in place; Level 2 focuses on bringing the power of analytics towards E2E optimization across departments. Introduction of predictive analytics is the key thrust area for Level 2.

**Data acquisition & analytics**
Implementation of predictive systems require availability of large-scale historical data at one place to make it amenable for analytics. This could be achieved by:

- Integrating various shop floor and supply chain data feeds in a unified data repository. The data feeds could include shop floor systems (for example, e-Logbook, LIMS); machine data (for example, from SCADA); supply chain data (ERP); targeted sensors (for example, vibration sensors deployed to build condition-based monitoring solutions) etc.
- Instituting Machine learning models to optimize the outcomes

Today’s technology systems allow executing these 2 steps in parallel, with early analytics starting with limited data and then the quality of analytics improving as depth of data improves with time

**Process simplification**
At level 2, analytics on historical outcomes enable identification of the most optimal process parameters to achieve highest productivity—on yield, cycle time, and other quality parameters; and set up process controls to achieve these parameters on each run. This involves:

- Building Golden batch profiles through analytics on historical performance (yield, cycle time, quality parameters like dissolution, hardness etc)
- Creating operations profile on the equipment to achieve the desired parameters at each run and enable recipe-based operations
- Error proofing operations (for example, through visual confirmation and
alarms) to limit excursions from desired process parameter.

Solutions like AR enabled instruction, digital SOPs and checkers would also enable operators do their job first time right.

**Asset performance & automation:**
Level 2 sees the focus towards much higher reliability and productivity in asset performance and move towards automation of manual complex tasks. This level involves:

- Assuring higher uptime: through predictive maintenance capabilities (basis analytics on failure modes of equipment) to pre-empt and avoid breakdowns; and AI enabled assist systems for faster resolution of failures

- Enhancing productivity and quality through mechanization of complex processes like inspection, sampling, material transfer and completely mechanize in-suite operations—for example, in warehouse. COBOTs could also be utilized for repetitive tasks such as maintenance of HVAC systems, cleaning etc.

**People org of the future:**
Level 2 would necessitate strong upskilling of the teams, including:

- Deploying and leveraging analytics talent towards building optimization logic

- Strengthening shop floor organization towards data-based decision making. Autonomous operating teams, in the organization could become the norm, with end to end responsibility of outcomes from an area given to a team

- Remote working could also be enabled for non-shop floor functions by leveraging the digital data. Functions like supply planning, QA, document review etc. could be served through a remote shared service set up across sites

- On shop floor, machines with integrated controls (for example, coating) could be managed remotely through digital feeds and control systems, leading to changes in the deployment pattern of operating crew.

**Control tower**
Integration of data systems at Level 2 would provide integrated E2E visibility across functions (production, warehouse, quality, procurement, engineering etc.). This would enable significant shifts in decision making processes, including:

- Cross functional data enabled planning (for example, through a digital twin)—for example, order acceptance, integrated scheduling and inventory management

- Transparent performance review and optimization—for example, through a digital control tower

- Optimization of cost and productivity drivers—for example, inventory, consumables, utilities etc.

Three level 2 use cases: digital twin, site control tower, and integrated site scheduler could be particularly valuable for pharmaceutical companies

**Level 2 Use cases in action**
Exhibit 4 provides an illustrative example of ‘AI Golden Batch optimizer’ that could be used towards optimizing yield and cycle time.

Exhibit 5 provides an example where machine learning is leveraged to pre-empt the occurrence of breakdown and trigger required maintenance.

Exhibit 6 provides an example of a Digital twin solution in context of Pharma plant. This creates a virtual representation of plant’s assets and processes through statistical and physical models and could be used towards decision making through real time scenario creations. Digital Twin is often used towards decisions such as:

- Equipment utilization and capex planning

- Monthly manufacturing planning

- Scheduling
EXHIBIT 4 | AI-Based Performance Optimizer

Client context:
Increase cycle time variation due to minor stops and speed variation for a vial filling line for an Indian PharmaCO

SOLUTION AND TECHNOLOGY

Data Engineering
40,000+ data points inputted into one database suitable for machine learning model

ML Modelling
Random forest does scenario-simulations via 10,000+ decision-trees running concurrently

Feature Engineering
Identify optimal ranges for key variables that maximize cycle time identified via decision trees to drive action

Maintenance trigger
10 key variables influencing cycle time identified from random forest simulations

Vial and stopper dimensions and preventive maintenance are the two major themes driving cycle time

<table>
<thead>
<tr>
<th>Theme</th>
<th>Variable measure</th>
<th>Variable</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial Dim.</td>
<td>Average</td>
<td>Overflow capacity</td>
<td>80.4</td>
</tr>
<tr>
<td>Vial Dim.</td>
<td>Average</td>
<td>Weight</td>
<td>69.7</td>
</tr>
<tr>
<td>PMP</td>
<td>Days since PMP</td>
<td>Vial Capping</td>
<td>68.7</td>
</tr>
<tr>
<td>PMP</td>
<td>Days since PMP</td>
<td>Vega Conveyor</td>
<td>63.3</td>
</tr>
<tr>
<td>Stopper Dim.</td>
<td>Average</td>
<td>Head Diameter</td>
<td>60.3</td>
</tr>
</tbody>
</table>

Source: BCG experience.

EXHIBIT 5 | Predictive Maintenance

Client context:
Injectable formulation site of global pharma manufacturer with frequent breakdown on heating tunnel of filling line

SOLUTION AND TECHNOLOGY

Model Input Design
70 Derived features from tunnel sensor data

Inputs
Sensor data from Sep’18 to Nov’18 for prediction

Output
Classifier random forest model to predict breakdowns

Combined
Separate models prepared for prediction windows of 2, 4, 12 and 24 hours

OUTPUTS
🌟 Top 3 features for breakdown prediction
- Average of Cooling Zone 1 airflow in past 2 hours
- Max make up zone 1 airflow in past 2 hours
- Deviation in Cooling Zone 1 airflow in past 4 hours
🌟 Probability of breakdown for the prediction window

Source: BCG experience.
Redeployment of resources

**LEVEL 3: PRESCRIPTIVE SYSTEMS AND CONTROL LOGIC DRIVEN PROCESS OPTIMIZATION**

Level 3 would see the analytics system evolving from being predictive (basis assessment of historical outcomes) to being prescriptive. The control systems would evolve to assess real time performance status, build scenarios of potential outcomes, and prescribe the most optimal course of action executed through real time feedback loops. The product quality would become an integral part of outcome (rather than as parameters that need to be tested post-facto). The evolution would be driven by progress along all 5 operating pillars, outlined below:

Data acquisition & analytics
The machine learning algorithms would couple with control logic and feedback loops to bring real time optimization. Tech stack would evolve towards:

- Including parameter-wise optimal profiles of outcome
- Incorporating real time assessment for each batch / process
- Building control logic and synchronous feedback loops to reset parameters

Process simplification
Level 3 would see processes being controlled through synchronous loops, which would involve:

- Validating control logic (versus validating robustness of a fixed, pre-defined process to deliver a desired output)
- Integrating quality as a default part of manufacturing (versus testing for output parameters at end of manufacturing process)
- Enabling a wider variability in input parameters (for example, raw material specs, process specs, asset parameters etc.) with a combination that drives the desired output
The controls will ensure that only exceptions are taken up for review by operating team. Prescriptive systems would also allow for parametric real time product release. Development of such process parameters would involve close engagement of product development, manufacturing and quality teams, to determine effective control logic.

Asset performance & automation
At Level 3, analytics would allow leveraging simulations of machine runs to enhance productivity, quality and compliance, including:

- Tracking impending breakdowns and failures in advance and take corrective actions
- Simulating scale up and tech transfer scenarios to enhance productivity
- Integration of lines (for example, filling and packaging lines) and move towards continuous operations (for example, coaters) will enhance productivity for organizations

People org of the future
As Quality become an integrated part of the manufacturing process in Level 3, the organization structures would also see a significant integration:

- Increasing collaboration across functions (manufacturing, quality and development) towards ensuring robustness of the process control logic
- Restructuring of operating roles—for example, QC moving away from product testing roles to parametric release
- Transitioning of multiple shop floor roles to remote operations—for example, control of machines through central Operations Command Rooms, focused on monitoring of the run versus the control logic driven parameters

The organization would involve significant digital upskilling of the operating crew, to run the processes remotely and basis the control logic; along with redesign of the entire performance management systems

Control tower
At level 3, the control tower starts optimization of decisions across the entire network and incorporating all organization functions (including beyond the site)—for example, R&D.

- Creating transparency across the network (for example, all API and Formulation sites)
- Creating integrated optimization across functions (for example, manufacturing, R&D, technology transfer etc)

With availability of org wide data, companies could achieve organization wide optimization—for example, E2E network optimization, distribution system optimization, throughput at a network level etc.

Use case in action:
Exhibit 7 demonstrates a control tower that integrates data from various sources spread across the supply chain to provide real-time visibility and optimization to prevent any supply disruption to customer

Level 4: Lights Out Plant
At level 4, various core pillars will come together to deliver an automated, integrated and optimized manufacturing system, managed by digital and technical experts with the ultimate objective of achieving a “Lights Out” plant.

The Lights out plant would be characterized by:

- Synchronous feedback loops along a multi-point optimization logic
- Plug and play modular processes that allow combinations of different equipment to manufacture different products
- Highly reliable assets, with predictability of performance and ability to control remotely, with minimal physical intervention by human during the run time
As companies transition to “Lights Out” plants / section, workforce will be transformed into a lean organization of dedicated technical and digital experts (for example, process scientists).

Companies will also initiate data integrations with suppliers and customers that would allow real time decisions for the overall ecosystem.

Digital Use Cases Along The Maturity Framework
In this journey, different digital use cases would need to come together at different levels to drive integrated outcomes. An illustrative set of such use cases is laid out in Exhibit 8

Roadmap and Impact
Globally, many organizations have embarked on small scale pilots of different use cases in different parts of their networks. Their experience suggests that it is crucial to upfront set-up a right aspiration on the maturity grid, at a site level. Setting the aspiration depends on the digital starting point of a plant, and the strategic objectives in medium term. For example, a legacy First Generation site could aim to reach level 2 and attempt level 3. While for a Next Gen plant, the aim should be to reach level 3 and strive for level 4 in certain sections.

Such a journey could drive significant improvement in manpower productivity, yield, OEE, OTIF, deviations per batch and conversion cost outcomes. While the exact impact would be different for different sites considering the starting point, a typical magnitude of impact is laid out in Exhibit 9.

A full scale journey towards building the future manufacturing function could be a 2+ year process. As a starting point, companies should conduct a maturity assessment of their sites to identify current technical capability and lay out strategic objectives and aspirations on the maturity grid. Subsequent to the assessment, a more detailed
EXHIBIT 8 | An Integrated Approach to Describe the Journey vs. Sporadic Use Cases for Enabling The "Future of Work" for Manufacturing

Source: Expert discussions, BCG analysis.

Step-jump in capability

Level 4
- Lights out sections/plant
- Plug and play production systems with platform archetypes linked to development
- Techno-digital experts
- Ecosystem Control Tower and Optimizer

Level 3
- Parametric control and feedback
- Real time PAT quality
- Process robustness – CPP range and parameters

Level 2
- Analytics data lake
- Full data integration - LIMS, MES, Historian, ERP, SCADA etc.
- Outcome predictor

Level 1
- Foundation data systems: E-logbook, E-BMR, LIMS
- BMR free of manual entry

DATA ACQUISITION, ANALYTICS

PROCESS SIMPLIFICATION

ASSET PERFORMANCE & AUTOMATION

ORG OF THE FUTURE

CONTROL TOWER

EXHIBIT 9 | Basis our Experience, We Expect Significant Impact Potential Through this Journey

Impact potential depends on starting point of the site on outcomes & digital maturity

Category | Performance Metric | Level 1 | Level 2 | Level 3 | Level 4
--- | --- | --- | --- | --- | ---
Source of estimates | Perf. of avg India site | Extrapolation from pilots at India sites & global examples | Productivity at global sites with large digital int. | Small scale pilots at global sites: 3-5 product blocks

People & asset productivity

Mfg doer productivity\(^1\)
(# of doers / 1000 batches) | 80-120 | 65-75 | 50-60 | 40-50
Yield | 92-96% | 95-97% | 96-98% | 98%+
OEE | 40-60% | 60-65% | 65-75% | 70-80%

Reliability

OTIF | 60-85% | 80-90% | 90-95% | 95%+

Cost

Conversion cost ($ per 1000 tablet) | 5.5-8 | 4-5.5 | 3.5-4.5 | 2.5-4

Source: Expert discussions, BCG analysis.

\(^1\)Includes only manufacturing related doers.
road map could be charted with different use cases being implemented in conjunction over time. A typical journey is laid out in Exhibit 10.

Embarking on The Journey—Our Perspective

As companies think about embarking on the journey, we believe they should consider 5 important aspects during the design of their transformation program:

- **Business Value Focus.** Lead journeys around high impact ‘Value Strikes’ (delivering business imperatives like productivity, growth) while laying the foundations for future.

- **Quick wins.** Deliver early wins to fund the journey and mobilize the organization.

- **Change management is key.** While tools and data are critical, transformation journey would deliver value through intensive change management.

- **Upskill team.** Creating internal capabilities to drive transformation and continue the journey core to success of the program.

- **Value steering for partners.** Technology is available in abundance to support the journey and need not be build inhouse. Many initiatives could be delivered through external partners with a robust value steering.

**WE ARE CONFIDENT** that the Future of Work in Operations could unlock significant value for the industry and be an ongoing source of competitive excellence globally.

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**Exhibit 10 | Future of Work—Manufacturing: Roadmap for Implementation**

<table>
<thead>
<tr>
<th>Level 1: Deploy Base Systems</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting point</td>
<td>6-9 months</td>
<td>1.5-2 year</td>
<td>2+ years</td>
</tr>
</tbody>
</table>

- **Level 1:**
  - Standard work
  - Process simplification; local optimization
  - Base data capture systems; creation of data lakes
  - Multi-skilling

- **Level 2:**
  - Initiate descriptive analytics
  - Multi-skilled crews; with data & analytics literacy
  - Leverage data and digital solutions to:
    - Build E2E transparency
    - Error proofing
    - Optimize in an integrated manner
    - Selective mechanization

- **Level 3:**
  - Initiate predictive analytics with control logic execution.
  - Work with quality & product development for optimization.
  - Enablement of remote operations, with connected asset. Focus on asset reliability.
  - Quality integrated with operations. Exception based reviews.

- **Level 4:**
  - Build sections for Lights out execution.
  - Integrated network of supplier and customers.
  - Dedicated techno digital experts with digital competencies.

*Source: BCG analysis.*
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