Achieving Maximum Production Efficiency

By Jim Mossop
Fette Compacting America, Inc
Future of Pharmaceutical Production

The future of pharmaceutical production will need to be more **flexible, faster** and above all **less expensive** than before – in other words:

**More Efficient**
The Future of Pharmaceutical Production

The global pharmaceutical market is facing fundamental changes. While during the boom times companies were mainly concerned with growing faster than their competitors, recent years have been characterized primarily by enormous cost pressure. The future is also anything but rosy.
The Benefits

Some of the benefits of “Achieving Maximum Production Efficiency”

• Shorter down-time and changeover times
• Greater machine availability
• Increased degree of capacity utilization
• Improved quality
• Better cost effectiveness of plant
• Increased yields
The Four Components

To achieve production efficiency concentrate on four core components.

The four key components are:

- Tool Management
- Maintenance Management
- Customized Training
- Production Excellence
Four Central Components

- Tool Management
- Customized Training
- Maintenance Management
- Production Excellence
Tool Management

Contents of Analysis for Tool Management:

• Employees

• Punch storage (arrangement and handling)

• Equipment for cleaning, polishing and measuring

• Handling

• Logistics

• Repeatability according to FDA and GMP
Tool Management

- Upper and lower punches
- Segments and dies
- Multiple tools and unusual formats
- FEM analysis for determining maximum compression force
- EU/TSM standardization permits use on all presses
Impact of Press Tooling

Effects

- Tablet quality
- Performance/Output
- Product loss
- Maintenance costs
Two Systems

- Dual tooling configurations:
  - Traditional turret = dies & punches
  - Fette segmented turret = segments & punches
- Careful matching of material & hardness
- System functionality
- High tablet quality
- Low sRel of compression forces
Important Dimensions – Standard Die

Taper Features:

- Escape of the excess air
- Minimization of ejection force
- Minimization of frictional heat
Tablet Design Drawing

- With 3-D-View
- FEM-Analysis available

Advantages:
- Visualization of the future tablet
  - Avoids additional changes
- Visualization of weaknesses
  - Changes of the design possible before actual production
Special Options for Max Performance

Fette Compacting EU1”-441 punch head:

- Longer dwell times
- Reduced capping problems
- Higher output
- Reduced vibration
- Reduced wear on tooling and machine
- Reduced noise
Additional Options

- Shaft diameter 28, 35, 45 mm – EU28, EU35, EU45
- Roller guided punches
- Punch holder with inserts
- Steel and tungsten carbide inserts
- Tungsten carbide dies
- Anti-sticking solutions
- Multi tip tooling
- Unusual shapes
- Variety of coatings
The Right Choice – Increasing Productivity

- Increased output with segments + additional increase with multi-tip tooling
- Minimized product loss
- Set-up time reduced
- Useable on both sides due to tangential alignment
- Different fixing possibilities of tips – e.g. transverse pin
Multi-tipped Tooling

- Extensive range of shapes and designs for multi-tip tooling are possible
- Feasibility check is necessary
- Dies up to max. 37-punch tips at D-tooling with Ø 2 mm

<table>
<thead>
<tr>
<th>Tablet diameter</th>
<th>For “B” (EU19) - x-fold (max.)</th>
<th>For “D” (EU 1” and - 441) – x-fold (max.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 6 mm</td>
<td>4x</td>
<td>-</td>
</tr>
<tr>
<td>Ø 7 mm</td>
<td>2x</td>
<td>5x</td>
</tr>
<tr>
<td>Ø 8 mm</td>
<td>2x</td>
<td>4x</td>
</tr>
<tr>
<td>Ø 9 mm</td>
<td>2x</td>
<td>3x</td>
</tr>
<tr>
<td>Ø 10 mm</td>
<td>1x</td>
<td>2x</td>
</tr>
</tbody>
</table>
Contents of analysis for the Maintenance Management

• Existing infrastructure
• Employees
• Spare parts
• Time management
• Record keeping
• Calibration / Preventive Maintenance (PM)
• Maintenance and inspection management
• Emergency maintenance
Maintenance Management

Spare Parts and Upgrade Kits

- Guaranteed reliability and high-performance
- OEM spare and upgrade parts
- Machine-specific consumable parts packages
- Guaranteed long-term availability
- Consignment parts
Maintenance Management

Service Contracts & Documentation

• Remote support service contract
  Rapid assistance available
  24 hours / 7 days

• World-wide, customer-specific service – maintenance, inspection and calibration

• Inspection and documentation to standards

• Documentation packages

• Materials certificates
Preventive Maintenance

Definitions of Preventive Maintenance (PM)....

- To protect against failure.
- To take precautionary measures.
- To perform scheduled maintenance.
- Use a PM checklist to document all work completed.
Preventive Maintenance

PM is not...

• Major repair work.
• Repair of unexpected breakdown.
Preventive Maintenance

When should P.M. occur?

• Every day during press operation.
• During product changeovers.
• During scheduled downtime specifically intended for maintenance.

All three are part of a successful PM program!
Preventive Maintenance

Who should be responsible for performing PM?

- Machine operators.
- Set-up personnel. (mechanics)
- Maintenance personnel.

All individuals listed share the responsibility!!
Preventive Maintenance

What’s needed to ensure PM gets done?

Commitment from all levels of organization:

• Management’s understanding of the importance of PM.
• Production planners must resist temptation to “skip it”.
• Regulatory requirement - Good SOP’s!
• People performing work diligently – well trained.
Training

Contents of analysis for Training:

• Level Based Training (LBT)
• Customized training
• VR Train
• Certification / Re-certification
Training

Many variations...

- Level Based Training (LBT)
- Training at the modern Fette Compacting training center
- Training at the customer's site
- Practically oriented know-how for beginners and advanced users
- Customer-specific
- GMP-conform personnel qualification according to 21 CFR Part 11 § 211.25

Consultation and training
General Overview –
Level-Based Training Program

- Based on progressively tiered model
- Each level includes “hands-on” and classroom sections
- Progress to successive levels requires participants to pass a written and practical assessment to ensure understanding
- At completion of each level, participants are issued a certificate and entered into Fette’s database for future reference
Production Excellence

Contents of analysis for Production Excellence:

• Analysis of process parameters
• Analysis of product handling
• Cleaning time and changeover time
• Model of shifts
• Performance of machine
• Increased output
• Optimization of products
• Optimization of human resources
Production Excellence

Ongoing Consultation

- Technical consultation with highly qualified engineers
- Practical demonstrations and product presentations
- Needs analyses
- Selection of machines and peripherals
- Process optimization
Optimized Processes

Well-advised At Every Stage

• Production-specific modifications
• Process and machine optimization
• Introduction of new products
• Production analyses
• Project planning
• Project execution
Better Continuity

For Higher Profitability

- Cost reduction through Process Analytical Technology
- Production that is analyzed and monitored
- Reduction of production cycle times through the use of on-line and in-line measurements
- Improved tablet quality due to real-time feedback regulation
Design Features for Increased Production

standard design

segment design
Reduced Cleaning Time

- No screw holes or die bores
Simple Is Better

Peak Performance With Segments

- Increased productivity
- Increased number of stations per turret
- No dies or die screws
- Significantly improved cleaning
- Time consuming adjustment of dies to punches for special format tablets no longer required
- Shorter changeover time
- Minimized product loss
- Improved tablet quality
- Longer life time
## Segment Benefits - Case Studies

<table>
<thead>
<tr>
<th>Set-up Time</th>
<th>Client A</th>
<th>Client B</th>
<th>Client C</th>
<th>Client D</th>
<th>Client E</th>
<th>Client F</th>
<th>Client G</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Segments</td>
<td>240 min.</td>
<td>120 min.</td>
<td>40 min.</td>
<td>1.5 hours</td>
<td>50 min.</td>
<td>30 min.</td>
<td>35 min.</td>
</tr>
<tr>
<td>Without Segments</td>
<td>480 min.</td>
<td>180 min.</td>
<td>120 min.</td>
<td>3 – 4 hours</td>
<td>84 min.</td>
<td>60 min.</td>
<td>65 min.</td>
</tr>
<tr>
<td>% time savings</td>
<td>50%</td>
<td>33%</td>
<td>66%</td>
<td>50%</td>
<td>41%</td>
<td>50%</td>
<td>47%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cleaning Time</th>
<th>Client A</th>
<th>Client B</th>
<th>Client C</th>
<th>Client D</th>
<th>Client E</th>
<th>Client F</th>
<th>Client G</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Segments</td>
<td>240 min.</td>
<td>300 min.</td>
<td>60 min.</td>
<td>52 min.</td>
<td>20 min.</td>
<td>25 min.</td>
<td></td>
</tr>
<tr>
<td>Without Segments</td>
<td>480 min.</td>
<td>480 min.</td>
<td>120 min.</td>
<td>88 min.</td>
<td>180 min.</td>
<td>60 min.</td>
<td></td>
</tr>
<tr>
<td>% time savings</td>
<td>50%</td>
<td>62%</td>
<td>50%</td>
<td>40%</td>
<td>90%</td>
<td>59%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Output - Tablets per Hour</th>
<th>Client A</th>
<th>Client B</th>
<th>Client C</th>
<th>Client D</th>
<th>Client E</th>
<th>Client F</th>
<th>Client G</th>
<th>Client H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before Segments</td>
<td>230,000</td>
<td>500,000</td>
<td>103,200</td>
<td>431,880</td>
<td>180,000</td>
<td>180,000</td>
<td>160,000</td>
<td>150,000</td>
</tr>
<tr>
<td>After Segments</td>
<td>285,000</td>
<td>700,000</td>
<td>189,000</td>
<td>448,200</td>
<td>220,000</td>
<td>200,000</td>
<td>170,000</td>
<td>180,000</td>
</tr>
<tr>
<td>% Increase</td>
<td>20%</td>
<td>29%</td>
<td>46%</td>
<td>4%</td>
<td>19%</td>
<td>10%</td>
<td>6%</td>
<td>17%</td>
</tr>
</tbody>
</table>
FS12 Segment Turret

- Up to 40% more output for the 3090 or 3200 press
- Turret with 110 stations, 66 stations or 45 stations
- Optimized punch head for long pressure dwell times
- Smooth machine operation due to the large number of punches engaged at all time
Description of the FS12 Punch

• Maximum tablet diameter: 11mm

• Maximum compression force: 25kN

• The other parameters stay unchanged
Definition of the FS12 Punch
**Practical Example**

- Higher capacities with constant machinery:
  - A: Multi-tip punches
  - B: 110 station turret with FS12 punch
## Comparison Profit Per Time Unit Pmax Segment Technology

<table>
<thead>
<tr>
<th></th>
<th>Tablet Press 1</th>
<th>Tablet Press 2</th>
<th>Tablet Press 3</th>
<th>Pmax / FS12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Stations</td>
<td>36</td>
<td>47</td>
<td>50</td>
<td>66</td>
</tr>
<tr>
<td>Punch type</td>
<td>EU19</td>
<td>EU19</td>
<td>EU19</td>
<td>FS12</td>
</tr>
<tr>
<td>Run time [h]/shift</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Shifts /day</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Turret rotation speed [rpm]</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>70</td>
</tr>
<tr>
<td>Output/hour [pieces]</td>
<td>151.200</td>
<td>197.400</td>
<td>210.000</td>
<td>277.200</td>
</tr>
<tr>
<td>Output/day [pieces]</td>
<td>1.814.400</td>
<td>2.368.800</td>
<td>2.520.000</td>
<td>3.326.400</td>
</tr>
<tr>
<td>Workdays/year</td>
<td>220</td>
<td>220</td>
<td>220</td>
<td>220</td>
</tr>
<tr>
<td>Profit/tablet [€]</td>
<td>0,001 €</td>
<td>0,001 €</td>
<td>0,001 €</td>
<td>0,001 €</td>
</tr>
<tr>
<td>Profit/h [€]</td>
<td>151 €</td>
<td>197 €</td>
<td>210 €</td>
<td>277 €</td>
</tr>
<tr>
<td>Profit/day [€]</td>
<td>1.814 €</td>
<td>2.369 €</td>
<td>2.520 €</td>
<td>3.324 €</td>
</tr>
<tr>
<td>Profit/year [€]</td>
<td>399.080 €</td>
<td>521.136 €</td>
<td>554.400 €</td>
<td>731.280 €</td>
</tr>
</tbody>
</table>
Quick Changeover Technology

Changeover definition:

*The compression of product “A’s” last tablet to the compression of the first tablet of product “B”*
Quick Changeover Technology

Factors involved:
• Labor hours
• Cycle time
• Scheduling
• Equipment
• Training
• Extra parts
Ask these questions:

- *How do changeovers impact your operation?*
- *Do you have changeover standards?*
- *Are you tracking performance vs. standard?*
Quick Changeover Technology

Also ask these questions:

- Do you have consistency in changeovers?

- If changeover reduction is a goal, where do you begin?

![Changeover Times Graph](image)
**WASH IN PLACE**

**The Concept**

*Automatic Initial Cleaning*

Highly efficient initial cleaning depending on product

- Time saving
- Easily repeated process
- Easy validation
Quick Changeover Technology

Removing turret from the machine:

- Eliminates tool and die removal
- Die table cleaning
- Cam removal and installation.
Quick Changeover Technology

- Exchangeable turret adds flexibility
- Tool and die work can be done outside of critical path or cycle time
Automated Turret Cleaner
Site Installed And Implemented New Processes & Equipment

- Turret & Tooling Room
- Tooling & Parts Cleaning (automated)
- Turret Cleaning (automated)
- Tooling Inspection & Maintenance
- PM Program (automated tracking)
- Calibration (automated tracking)
- Certification Training (LBT)
- New Tablet Compression Suites
Changeover Statistics

Avg. Changeover Time

<table>
<thead>
<tr>
<th>Year</th>
<th>1995-96</th>
<th>2000-01</th>
<th>2005-06</th>
<th>2010-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
<td>25</td>
<td>15</td>
<td>7</td>
<td>12</td>
</tr>
</tbody>
</table>

- 1995-96
- 2000-01
- 2005-06
- 2010-11
Headcount Statistics
Machines Needed to Meet Production

TOTAL MACHINES

- Number of Machines
- Non-Fette presses
- Fette presses


-2  0  2  4  6  8  10  12  14
Changeover Times Using Additional Turret

Advantage of the Removable Turret

Number of Changeovers

- Number of changeovers
- Number of products
- Avg. Changeover time

Year

Productivity Per Machine

- **Average tablets per hour (1,000)**
- **Average Volume per machine**


Graph shows the productivity per machine over time, with an increase from 1995-96 to 2010-11.
Overall Productivity

Productivity

- Number of batches/operator
- Number of changeovers/operator
- Productivity per Operator
Additional Advantages

• Reduced parts inventory
• Standardized training
• Standardized S.O.P’s
• Scheduling
• Any product mix including bi-layer
• Standardized PM’s & calibration
• Reduced validation efforts
• Reduced floor space required
Fette Compacting America

Thank you for your time!