SOFTGEL MANUFACTURING: Experience-Based, Applied Technology with Cost-Effective Direction

Scientific Advancements in Softgel Technology That Will Drastically Change Manufacturing

Presented by:
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VP - CHANGSUNG
Meanwhile...
we change the paradigms of softgel technology
Softgel Manufacturing has Kept the Same Paradigm for Many Years

Die Roll Encapsulation Machines

Seamless “Round-Only Capsule” Machines
How Do We Reduce the Cost of Softgel Manufacturing?

First, we need to identify some of the most critical points that hit any softgel manufacturer’s costs directly:

- Specialized Operators
- Time and Space
- Encapsulation and Drying Speed
- Gelatin International Price Increase

Of course, there are many other variables involved... but we want a general overview.
How Do We Reduce the Cost of Softgel Manufacturing?

To reduce costs, we must address the following:

1. Reduction of Specialized Expertise and Operator Interaction (no artists)

2. Operational Excellence (Time and Space-saving Operations)

3. High-Speed Encapsulation and Drying

4) Gelatin Use, Optimization, and Recovery
Modern process control and automation:

- Automatic Die Roll Synchronization
- Automatic Encapsulation Machine Timing
- Automatic Fill Weight Control
- Automatic Ribbon Thickness Control
Many different techniques have been used to make sure the die rolls perfectly match

- Magnifiers
- Mechanical Gadgets
- Mechanical Modifications
Perfect Die Roll Synchronization Assures:

- Correct seam rate
- Minimization or elimination of defects due to leaking capsules
Automatic Die Roll Synchronization:

- Ensures fast start up
- Eliminates causes of leaking
- Allows reliable and precise die roll mounting
Automatic Machine Timing:

- Eliminates the timing gear
- Allows faster operation due to simpler mechanics
- Allows consideration of viscosity
- Allows precise adjustment of injection timing
Automatic Fill Weight Control:

- Faster start ups
- Density considered
- Precise set up of the specific fill weight
- Electronic encoder adjusts any minimal variation
- Allows the use or 2 or more plungers in one capsule
- Reduces the process control frequency
Automatic Gelatin Ribbon Thickness Control:

- Faster start ups
- Reduces the process control frequency
- Reduces shape-defective product
- Improves Seam Rate Uniformity
- Reduces Operator Interaction.
CASE:
“Brazilian Pharmaceutical Company X”
Nov. 2013

Background: No previous experience in the softgel process
Product: Multivitamin with minerals
Operation: Operators trained from scratch lead by a supervisor with elementary 24 month training

Specifically designed manufacturing line investing in:
- Space saving operations
- Automatic gelatin ribbon adjustment
- Automatic fill weight adjustment
- Automatic spreader box level adjustment
- Automatic fill material and gelatin level monitoring
Reducing the operator interaction in the critical process control achieved:

- Implementation of the line producing quality product within 1 week
- Implementation of process controls for qualification within 1 week
- Reached 95% performance within 30 days of manufacturing
- Increased the performance to 98% as standard within 6 months
- Implemented the continuous non stop manufacturing before 1 year of operations.
Background: No previous experience in the softgel process

Product: Wide variety of oil, paste and hydrophilic products

Operation: Operators trained from scratch within intense training for 2 months leaded by consultant expert.

3 Lines designed for medium size batches (300K caps to 500K caps):
- Space saving operations, gravity feed
- Automatic gelatin ribbon adjustment
- Automatic fill Weight adjustment
- Automatic spreader box level adjustment
- Automatic fill material and gelatin level monitoring
Reducing the operator interaction in the critical process control achieved:

- Installation of the first line produced quality product within 1 month
- Installation of the second line produced quality product within 6 months
- Installation of the third manufacturing line produced quality product within 12 months of the first one
- Implementation of process controls for qualification within 1 week per line
- Reached 98% performance within 30 days of manufacturing for every line
- Achieved IQ, OQ, and validation of the first 2 lines, and obtained GMP certification and license less than 12 months after the 1st line was installed
LONG STARTS COST MONEY

Just because of gelatin 10 USD/kg

Long start ups cost money

COST OF START UP PER MACHINE

<table>
<thead>
<tr>
<th></th>
<th>3rpm</th>
<th>12 kg/hr</th>
<th>6rpm</th>
<th>24 kg/hr</th>
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<tbody>
<tr>
<td>minutes</td>
<td></td>
<td>USD$</td>
<td></td>
<td>USD$</td>
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<td>120</td>
<td>$480.00</td>
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Calculation under 300 working days per year, only the difference over 30 minutes
2 shifts per day

COST OF LONG START UP PER MACHINE

<table>
<thead>
<tr>
<th>Difference</th>
<th>3rpm</th>
<th>6rpm</th>
<th>3rpm</th>
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</table>
High speed softgel encapsulation is mainly limited by:

- The plunger pump mechanical paradigm
- Flow dynamics
- Drying time
High Speed Encapsulation

CASE OF EUROPEAN FISH OIL MANUFACTURER:

- Implemented High Speed Encapsulation
- High speed machine same size and die roll as usual
- Increased speed from 3.5 to 6.5 rpm
- 98% performance
- Quality product with same seam rate
- Increased only 20 to 30% manufacturing floor area, with continuous drying
High Speed Encapsulation

CASE OF A KIWI NUTRACEUTICAL MANUFACTURER:

Implemented High Speed Encapsulation

- High speed machine same size and die roll as usual.
- Increased speed from 3.5 to 6.5rpm for oils.
- Increased speed from 3rpm to 5rpm for pastes
- 98% performance
- Quality product with same seam rate
- Increased only 20 to 30% manufacturing floor area, with continuous drying
Without Changing the Paradigm

We reach interesting solutions:

• Increase the number of plungers to share in one capsule
• Require reduction of the stroke distance
• Optimize the plunger diameter
• Optimize the flow dynamics design
• Reinforce the mechanics to hold more stress
• Focus on the specific product
• Increase the speed without increasing the machine size
Without Changing the Paradigm

ONE OF THESE SOLUTIONS IS THE DOUBLE DECKER PUMP:

- Allows us to use the same machine size
- Delivers precise volume in a shorter period of time
- Reduces the stroke required
- Increases precision
- Some machines can be retrofitted
Plunger Size Optimization

If want to use more than two plungers to fill out one capsule...

The plunger size matters

We need to meet the precision, and minimize the return

<table>
<thead>
<tr>
<th></th>
<th>Plunger Diameter mm</th>
<th>Volume one plunger mm³</th>
<th>Stroke mm</th>
<th>Number of plungers per cavity</th>
<th>volume displaced mm³</th>
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<tr>
<td>A</td>
<td>11</td>
<td>999.75</td>
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<td>5.58</td>
<td>3</td>
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<tr>
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<td>474.58</td>
<td>7.46</td>
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<td>949.17</td>
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</table>
Plunger Size Optimization

We have to design the die roll and injection system according to the set of plungers available

<table>
<thead>
<tr>
<th>Capsule rows in the die</th>
<th>Used plungers per type A</th>
<th>Return Plungers</th>
<th>volume returned ml</th>
<th>Capsule rows in the die</th>
<th>Used plunger per type B</th>
<th>Return Plungers</th>
<th>Volume Returned ml</th>
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<td>2</td>
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<td>8</td>
<td>7998.0</td>
<td>15</td>
<td>2</td>
<td>2533.10</td>
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<td>28</td>
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<td>10</td>
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<td>2</td>
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<td>3</td>
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<td>2</td>
<td>1999.5</td>
<td>6</td>
<td>6</td>
<td>633.27</td>
</tr>
</tbody>
</table>

Calculation done for a 6 inch diameter 10 inch long die roll
Minimization & Elimination of the Return
## Proving the “Short Stroke” Principle

<table>
<thead>
<tr>
<th>Weight fill control for 1000mg capsule</th>
<th>7 x 34</th>
<th>238 cavities per revolution</th>
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<tbody>
<tr>
<td>11mm diameter plungers 2 per capsule</td>
<td></td>
<td>8.5mm plungers 3 per capsule</td>
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<tr>
<td>20 plungers per pump</td>
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<td>38 plungers per pump</td>
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<tr>
<td>2 plungers per cavity</td>
<td></td>
<td>5 plungers per cavity</td>
</tr>
<tr>
<td>14 plungers used</td>
<td></td>
<td>35 plungers used</td>
</tr>
<tr>
<td>6 returns</td>
<td></td>
<td>3 returns</td>
</tr>
<tr>
<td>Volume returned</td>
<td>2999.2 mm³</td>
<td>949.91 mm³</td>
</tr>
<tr>
<td>Density of material</td>
<td>0.96 gr/cm³</td>
<td>0.96 gr/cm³</td>
</tr>
<tr>
<td>10.525 mm stroke</td>
<td></td>
<td>3.524 mm stroke</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Plun/cav</th>
<th>Plun/cav</th>
<th>Plun/cav</th>
<th>Plun/cav</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plun/cav</td>
<td>diameter</td>
<td>stroke</td>
<td>Plun/cav</td>
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<td>3</td>
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<td>Average</td>
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<tr>
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<td>0.008</td>
<td>0.0075</td>
<td>0.002</td>
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</table>
Gelatin Cost, and its Recovery

Gelatin has almost doubled in price over the last 5 years.

In the past, there have been some recovery techniques for the scrap net:

1. Direct remelting and separation.
2. Milling, washing with solvent, centrifugation and remelting.
3. Milling, washing with chilled water, super centrifugation and remelting.

Use or recovered gelatin ratios:

20% virgin + 80% recovered for 1st row net
40% virgin + 60% recovered for 2nd row net
Gelatin Cost, and its Recovery

Some disadvantages of the old techniques:

- Viscosity breakdown
- No control over the molecular weight of the gelatin
- Revolved process with complex operation control
- Use of solvents
- Segregation of colored and translucid gelatin
- Very different desintegration times than virgin gelatin.
IT'S NOT NEW; IT IS A TECHNOLOGICAL CONCEPT BREAKTHROUGH

Recovering the gelatin net with Micro filtration and Ultra filtration (MWCO, Molecule Weight Cut-Off)

Advantages:

- No Milling Required
- No Solvents Required
- No Viscosity Breakdown in the Resulting Material
- Molecular Weight of the Gelatin is Preserved
- 90 to 99% Performance in the Material Recovered
Gelatin Cost, and its Recovery

Centrifuge

Re-melting
WE HAVE TAKEN A PART OF THE EXISTING MODERN GELATIN MANUFACTURING PROCESS

- Remelting the gel, and dilute it to a 6% concentration
- Filtration
- Micro Filtration
- Ultra Filtration
- Deionization
- Final Ultrafiltration

= Result 27 to 30% Translucid Gelatin Solution.
How it Works:

We have taken a part of the existing modern Gelatin manufacturing process, and slightly changed the order.
Procedure

5% ~ 10% of diluted solution of gelatin net (Gelatin, Glycerin, Water and additives included)

Gelatin Reclalm System

20% ~ 30% of refined gelatin solution (Gelatin and Water only)
MICROFILTRATION
Particle size exclusion separation with micro ceramic filters

- Lubricating Oil
- Residual Hydrophobic Fills
- Haze Components
- Suspended Solids
- True Emulsions

6% Gelatin NET Solution

- 6% Gelatin
- Glycerin / Sorbitol (plasticizers)
- 20pp to 300ppm
- Water
Ultra Filtration 1
MWCO (Molecular Weight Cut-Off)

Water, Glycerin, Unwanted Low MW Geltain, and others.

- 6% Gelatin
- Glycerin / Sorbitol (plasticizers) 20pp to 300ppm
- Water

UF1 Membrane

Recovered correct MW Gelatin and water soluble colors.
Deionization
Resin Ion exchange color removal

- 6% Gelatin
- Glycerin / Sorbitol (plasticizers)
  20pp to 300ppm
- Water

Recovered correct MW Gelatin
6% Solution

Recovered correct MW Gelatin
and water soluble colors.

Water, hydrosoluble color
ULTRA FILTRATION 2
MWCO (Molecular Weight Cut-Off)

- Water and other smaller molecules
- Recovered correct MW Gelatin 6% Solution
- Recovered 27% to 30% Gelatin water sol.
What Do We Get?

A gelatin solution concentrated enough to be handled, with a molecular weight that is 95% to 99% equal to the virgin gelatin.
What Do We Get?

Recovered gelatin by other methods won’t match
How Do We Know if it Will Work for Capsules?

1. By looking after the molecule structure with HPLC

2. By checking the quality of the softgels done with the recovered gel.
   - Seal Strength
   - Capsule Strength
   - Adhesive Property

Extensive studies have been done in the USA by B.S. and R.C. with a similar recovery technology.
REMELTING TO 6% SOLUTION

GTM (Gel Net Tank for Melting)

Material: Inner jacket SS316 / outer jacket SS304
Electric cartridge heater for circulation water
Stirrer speed: 40 RPM maximum
Max temperature: 99 degree Celsius
MF (Micro Filtration System)

Specification

- Pore size: 0.8 μm
- Ceramic filter
- Semi automatic operation
- Ceramic module and housing
- Frame and CIP tank
- Feeding pump, Circulation pump
- Back flushing unit
- Automatic and manual valve
- Flow meter, Heat exchanger
- Touch screen control panel with PLC
UF (Ultra Filtration System)

Specification

Spiral type
Automatic operation
Frame and CIP tank
Feeding pump
Circulation pump
Automatic and manual valve
Flow meter
Touch screen control panel with PLC
DS (Decoloration System)

Specific resin type for color removal
GRS 4000S Flow sheet

1. TK1 2000L
2. Micro filtration system
3. TK2 2000L
4. 1st U/F Concentration system
5. 2nd U/F Concentration system
6. TK3 2000L
7. Decoloration system A/B
8. TK4 2000L
9. Decoloring system

<table>
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<th>NO.</th>
<th>DESCRIPTION</th>
<th>SIZE</th>
<th>Q'TY</th>
<th>MAT'L</th>
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<td>Gelatin Melter 1000L</td>
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<tr>
<td>2</td>
<td>Micro Filtration System (50SQ)</td>
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<td>3</td>
<td>1st U/F Concentration system</td>
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<td>4</td>
<td>2nd U/F Concentration system</td>
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<tr>
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<td>Holding Tank</td>
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<td>Decoloration A/B</td>
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<td>1</td>
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</table>

Gelatin Reclalm system
# Gelatine Reclalm System

**Note:**
- Air: 5kg/cm²
- Hot DI Water: 1400 liters/hr
- 32ton/20hr
- Power: 5kW
- Discharge Oil and Suspended solid

## Dissolution 250kg/hr
- 2000kg/8hr, CIP/2hr
- TOTAL (4000kg/20hr)

## MF system (Microfiltration)
- DI & Diafiltration Water: 350 liters/hr
- CIP Water: 2000 liters/day
- Power: 35kW
- Air: 5kg/cm², 100 liters/hr
- Discharge Oil and Suspended solid

## UF system (Concentrated gelatin)
- Discharge Water and Glycerin: 5% - 28% gelatin
- CIP Water: 3000 liters/day
- Power: 15kW

## UF system (Decoloration)
- DI DF Water: 30,000 liters/20hr
- CIP Water: 3000 liters/day
- Power: 10kW

## DECOLORIZER (Decoloration)
- CIP & regeneration water: 10,000 liters/cycle
- Chemical Regeneration with NaoH: 6%
- 800 liters/cycle
- Power: 4kW
PILOT PLANT: South Korea, 2012
Flow Indicator
4,000Kg/day system during FAT, 2013
Housing

4,000Kg/day system during FAT, 2013
Installation

4,000Kg/day system during FAT, 2013
Filtration

4,000Kg/day system during FAT, 2013
Storage tank 4,000Kg/day system during FAT, 2013
Ultra filtration

4,000Kg/day system during FAT, 2013
4,000Kg/day system 3D view
75m² to 100m²
4,000Kg/day system New Zealand, 2014

Gelatin net

Loading gelatin net

Dissolving gelatin net
4,000Kg/day system New Zealand, 2014

2nd floor of MF SYSTEM
Purified and concentrated gelatin solution by UF1/UF2
Process of GRS system

Before MF

After MF

After UF1&UF2
How We Use it:

Regularly you use:

Gelatin 40%
Plasticizer 20%
Water 40%
Total 100%

Using recycled gelatin solution you will use:

Gelatin (New) ..........................10%
Recycled solution (30% gelatin.)........70% (40% of water is already in the solution)
Plasticizer 20%..........................20%
Total ........................................100%
Formulations May Vary

Depending on:

- Company operations and logistics
- Gelatin net used and gelatin origin
- Colored or non colored Gelatin
- UF1 and 2 cycle time
## How Much is Wasted?

Gelatin NET waste from 36% to 40% 6 inch diameter x 10 inch long with 0.8mm ribbon

<table>
<thead>
<tr>
<th>Machine Speed</th>
<th>Gelmass per hour (30 kg/hr)</th>
<th>Gel Net per hour (12 kg/hr)</th>
<th>Gelatin per hour (4.8 kg/hr)</th>
<th>Days per year (250)</th>
<th>Gelatin average</th>
<th>USD$ 10 Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rpm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gelatin average</td>
<td>USD$ 10 Kg</td>
</tr>
<tr>
<td>Hours per Shift</td>
<td>Kilos of gelmass per shift</td>
<td>Kilos of Gel Net per Shift</td>
<td>Kilos of Gelatin per shift</td>
<td>USD$ wasted per shift</td>
<td>USD$ wasted per year</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>210 kg</td>
<td>84 kg</td>
<td>33.6 kg</td>
<td>$ 336.00</td>
<td>$ 84,000.00</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>420 kg</td>
<td>168 kg</td>
<td>67.2 kg</td>
<td>$ 672.00</td>
<td>$ 168,000.00</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>600 kg</td>
<td>240 kg</td>
<td>96 kg</td>
<td>$ 960.00</td>
<td>$ 240,000.00</td>
<td></td>
</tr>
</tbody>
</table>

Gelatin NET waste from 36% to 40% 6 inch diameter x 10 inch long with 0.8mm ribbon

<table>
<thead>
<tr>
<th>Machine Speed</th>
<th>Gelmass per hour (60 kg/hr)</th>
<th>Gel Net per hour (24 kg/hr)</th>
<th>Gelatin per hour (9.6 kg/hr)</th>
<th>Days per year (250)</th>
<th>Gelatin average</th>
<th>USD$ 10 Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>6rpm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gelatin average</td>
<td>USD$ 10 Kg</td>
</tr>
<tr>
<td>Hours per Shift</td>
<td>Kilos of gelmass per shift</td>
<td>Kilos of Gel Net per Shift</td>
<td>Kilos of Gelatin per shift</td>
<td>USD$ wasted per shift</td>
<td>USD$ wasted per year</td>
<td></td>
</tr>
<tr>
<td>7</td>
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<td>168 kg</td>
<td>67.2 kg</td>
<td>$ 672.00</td>
<td>$ 168,000.00</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>840 kg</td>
<td>336 kg</td>
<td>134.4 kg</td>
<td>$ 1,344.00</td>
<td>$ 336,000.00</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>1200 kg</td>
<td>480 kg</td>
<td>192 kg</td>
<td>$ 1,920.00</td>
<td>$ 480,000.00</td>
<td></td>
</tr>
</tbody>
</table>
Cost varies depending on:

- Wages
- Energy cost
- Logistic costs and taxes

Most of the worst cases:

USD$1.2 to USD$2.00 per kilo of Recovered Gelatin
Thank you!

If you would like a copy of this presentation, please provide your email address or reach out directly to:

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becky@hillseth.com

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Or Visit us at Booth #1771
Anytime During INTERPHEX Exhibit Hours