FDA Meeting – 2016-10-14

Agenda

- Solution Provider Perspective
- How easy this is?
- Growth and Capacity
- Reality Check
- Aggregation…
- Recommendations
15,000

Packaging Lines needs Serialization

Unprecedented industry challenges to be faced within the next 5 years!
≈25%  

Lines Completed so far

Most of the tier 2, tier 3 players in the industry have not even started
Example of a fully Serialization and Aggregation “ready” packaging line
How easy this is?
Packaging Lines already exist
Competitors are working together!

OPEN SCS
Working Group

http://open-scs.org
Capacity and Growth
Optel Vision in numbers

**AMERICAS**
475

**EUROPE**
125

**ASIA**
50

- **North America**
  - Headquarters
- **Europe**
  - Limerick Facility
- **Brazil**
  - Campinas Facility
- **India**
  - Goa Facility
Capacities

Optel Vision – Capacity/Growth

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>75</td>
</tr>
<tr>
<td>2012</td>
<td>91</td>
</tr>
<tr>
<td>2013</td>
<td>117</td>
</tr>
<tr>
<td>2014</td>
<td>205</td>
</tr>
<tr>
<td>2015</td>
<td>375</td>
</tr>
<tr>
<td>NOW</td>
<td>539</td>
</tr>
<tr>
<td>2017</td>
<td>700</td>
</tr>
</tbody>
</table>
Capacity

Optel Vision’s Capacity Increase

Phase 1 - 2008 – 20 000sqft
Phase 2 - 2013 – 25 000sqft
Phase 3 - 2016 – 37 500sqft
Reality Check
Aggregation...
Bottle Aggregation is complex
Recommendations

- FDA to clarify *when* aggregation is needed
- Require aggregation but give an extra year to enforce the Dec 2017 milestone