## 2016 HPC Fall Meeting

**Friday, October 28, 2016**  
Montesi Room, 2nd Floor of Buckman Hall, Christian Brothers University  
650 East Parkway South, Memphis, TN 38104

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:45 a.m. – 9:15 a.m.</td>
<td>• Check-in/Continental Breakfast</td>
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</table>
| 9:15 a.m. – 10:15 a.m.| • **Medical Device Packaging Trends**  
                         |     *Paul Marshall, Smith & Nephew*                                   |
| 10:15 a.m. – 10:30 a.m.| • Break                                                              |
| 10:30 a.m. – 12:00 pm | • **Consumer Trends in Corrugated Industry and Packaging Design**   |
|                       |     *Srin Rajagopal & Alex Bevier, International Paper*              |
| 12:00 noon – 1:15 p.m. | • Lunch                                                              |
|                       | • **Funding the Commercialization of Innovation: The ins and outs of**|
|                       |     *investments*  
                         |     *Allan Daisley, ZeroTo510 Medical Device Accelerator*          |
| 1:15 p.m. – 2:45 p.m. | • **ISTA Thermal Laboratory Certification**  
                         |     *Sean June, Christian Brothers University*                     |
| 2:45 p.m. – 3:00 p.m. | • Break                                                              |
| 3:00 p.m. – 4:00 p.m. | • **Packaging R&D Projects @ CBU**  
                         |     *Pong Malasri, Christian Brothers University*                  |

Campus Map: [http://www.cbu.edu/assets/2091/cbumap2015.pdf](http://www.cbu.edu/assets/2091/cbumap2015.pdf)

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**Active Members**  
Bayer Consumer Care, Eette, Evergreen Packaging, FedEx, GlaxoSmithKline, International Paper, Medtronic, Memphis Bioworks, MicroPort Orthopedics, Olympus Surgical Technologies America, Smith & Nephew, SweetBio, Thaddeus Medical Systems, The Pallet Factory, Wright Medical
Meeting Sponsors

Smith & Newphew
(http://www.smith-nephew.com/)

International Paper
(http://www.internationalpaper.com/)

ZeroTo510
(http://zeroto510.com/)

Christian Brothers University
(http://www.cbu.edu)

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<table>
<thead>
<tr>
<th>Registered Participants</th>
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<tbody>
<tr>
<td>1. Aflaki, James</td>
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<tr>
<td>2. Bahudhoddi, Bharath</td>
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<td>3. Baker, Chad</td>
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<td>4. Bell, James</td>
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<tr>
<td>5. Bevier, Alex</td>
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<tr>
<td>6. Bonner, April</td>
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<td>7. Campbell, Christian</td>
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<td>8. Campbell, Hope</td>
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<tr>
<td>9. Cauley, Melissa (Simpson)</td>
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<tr>
<td>10. Chintalapati, Bulli</td>
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<tr>
<td>11. Daisley, Allan</td>
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<td>12. Deas, Jimmy</td>
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<td>13. Devabakthni, Yugesh</td>
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<td>14. Edwards, Evan</td>
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<td>15. Fondouop, Eric Defo</td>
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<td>16. Gadomski, Dick</td>
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<td>17. Garcia, Luis</td>
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<td>18. Gilman, Jay</td>
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<td>19. Graff, Kayla</td>
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<td>20. Housewirth, Jade</td>
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<tr>
<td>21. June, Sean</td>
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<td>22. Kneipp, Wayne</td>
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<td>23. Malasri, Pong</td>
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<td>24. Marshall, Paul</td>
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<td>25. Moats, Bob</td>
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<td>26. Ostrowski, Michael</td>
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<td>27. Phaneuf, Rob</td>
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<td>28. Rajagopal, Srin</td>
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<td>29. Ray, Asit</td>
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<td>30. Rodriguez, Isaac</td>
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<td>31. Rutledge, Larry</td>
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<td>32. Sheppard, James</td>
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<td>33. Stevens, Ryne</td>
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<td>34. Thomas, Erica</td>
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<td>35. Thota, Vinithraj</td>
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<td>36. Tummala, Leela Harshitha</td>
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<tr>
<td>37. Wellford, Brandon</td>
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<td>38. Whitaker, Marsalas</td>
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<td>39. Williams, James</td>
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Christian Brothers University
International Paper
ZeroTo510 Medical Device Accelerator
GSK
FedEx
Christian Brothers University
Smith & Nephew
MicroPort Orthopedics
FedEx
SweetBio
Christian Brothers University
Smith & Nephew
MicroPort Orthopedics
International Paper
Christian Brothers University
SweetBio
CBU ISTA Certified Packaging Lab
University of Memphis
Smith & Nephew
Christian Brothers University
Christian Brothers University
Memphis Bioworks
SweetBio
Smith & Nephew
Medical Device Packaging Trends

Paul Marshall

Abstract:

The industry continues to evolve and change. These changes are driven out of external and internal changes to improve quality and demonstrate compliance with regulatory, design control and quality requirements. These changes impact how medical packaging is developed, managed and how companies demonstrate compliance with new industry requirements. These changes also incorporate new and existing processes together to create holistic process to improve quality, reporting, and resource allocation to drive continuous improvement projects.

In this presentation, the following topic will be discussed:

- Medical Device Sustainability
- Sustainability Reporting and Analysis
  o Dow Jones Sustainability Index
  o Life Cycle Analysis (LCA)
- Establishing Acceptance Criteria
  o Minimum seal strength
  o Sample sizes
- Audit/Complaint Processes
  o Merging process to development comprehensive processes
  o Monitoring audit findings and complaints to find patterns
  o Developing continuous improvement processes
- Risk Mitigation
  o Adhering to ISO 14971 Requirements
  o Impact to packaging processes
- Future State
  o Vision systems for part identification
  o Technology implementation to drive continuous improvements

Keywords: Packaging Trends, Medical Device Packaging, Sustainability, Risk Mitigation, Sample Size, Complaint/Audit Process

Presenter:

Paul Marshall has over 20 years of experience within the packaging industry that covers a variety of different industries such as military/defense, retail, industrial, pharmaceuticals, and medical device packaging applications. The majority of his career has focused within the medical and pharmaceutical packaging sectors. Over his career, Paul has earned several awards for excellence in packaging development, including three Ameristar Awards, one Worldstar Award, and one US/International patent. Paul is a Certified Packaging Professional with Lifetime status (CPPL) and Project Management Professional (PMP). He has been employed with Smith & Nephew for the last four years as the Manager of Global Packaging Technologies. In his role, Paul is responsible for ensuring global compliance to global regulatory bodies packaging requirements. He also manages the Memphis Packaging Lab and supports testing for all sites globally. In addition, Paul manages both the Packaging Process Engineering and Packaging Sustaining Engineering teams across the US. In the past several years, Paul’s team has been responsible for developing sustainable packaging solutions that support Smith & Nephew’s business goals of improving the company’s position on the Dow Jones Sustainability Index (DJSI) and showcasing and communicating those successes as it relates to improved sustainability metrics.
### Trending in Medical Device Packaging

<table>
<thead>
<tr>
<th>Topics</th>
<th>Description</th>
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<tbody>
<tr>
<td>Sustainability</td>
<td>A big driver that not only helps our environment, but is also becoming a driver in tendering.</td>
</tr>
<tr>
<td>Acceptance Criteria</td>
<td>Establishing minimum acceptance criteria through testing rather than relying on past industry norms.</td>
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<tr>
<td>Audit/Complaint Processes</td>
<td>Developing processes that address and prevent complaints from reoccurring.</td>
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<tr>
<td>Risk Mitigation</td>
<td>New requirements that drive risk mitigations when solutions are available.</td>
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Sustainability – DJSI Medical Product – 2014

<table>
<thead>
<tr>
<th>Sustainability Leaders as of September 2014</th>
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<tbody>
<tr>
<td>Number of Members</td>
</tr>
<tr>
<td>Number of Companies in Invited Universe</td>
</tr>
<tr>
<td>Company</td>
</tr>
<tr>
<td>Abbott Laboratories*</td>
</tr>
<tr>
<td>Baxter International Inc</td>
</tr>
<tr>
<td>Boston Dickinson and Co</td>
</tr>
<tr>
<td>Medtronic Inc</td>
</tr>
<tr>
<td>ResMed Inc</td>
</tr>
<tr>
<td>Smith &amp; Nephew PLC</td>
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<tr>
<td>Stryker Holding AG</td>
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<tr>
<td>Syneron Corp</td>
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*Industry Leader  ○ Company in Invited Universe  ● Member of DJSI

* Now 35 members in the DJSI Universe opposed to 5 in 2014.
** Now 51 in the DJSI Universe opposed to 43 in 2014.
Sustainability – Optimization of the Packaging System

Sustainability:
– drives packaging optimization, lowering cost.
– fuels innovation with alternative material research and development.
– translates to cost savings opportunities.
– provides powerful success stories and positive metric reporting.

Sustainability – Metrics within Healthcare Industry

Hospital waste disposal costs skyrocketing
– 30 – 50% of hospital waste stream is packaging
– Transition from red bag waste to municipal waste stream

Societal and customer expectations to go green
– Hospitals becoming largest contributor to local landfills
– Corporate Environmental policy
– EPR: Extended Producer Responsibility (Tender and European mandates: Germany)

Manufacturers need to remain competitive in the market
– Return on Environment ROE
– Product differentiation
Sustainability – Benefits of Commitment to Sustainability

- Improved brand reputation: 28%
- Reduced energy costs: 26%
- Increased competitive advantage: 25%
- Reduced waste costs: 22%
- Access to new markets: 21%
- Increased margins or market share: 19%
- Improved regulatory compliance: 18%
- Better innovation of products/services: 17%
- Innovation of business models and...: 15%
- Reduced risk: 14%
- Enhanced stakeholder/investor relations: 10%
- Increased employee productivity: 5%
- There are no benefits: 2%

Source: MIT paper, Haanaes et al 2011

Trending in Medical Device Packaging
Acceptance Criteria – Industry Standards?

EN 868-5 (porous materials):
– 1.5N/15mm (0.57lb/in) for steam sterilization.
– 1.2N/15mm (0.47lb/in) for other sterilizations.

ISO 11607-1:
– Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.

“Industry Standards”
• 1 lb./in
• “This is what we always used”

Acceptance Criteria – LSL

Allows for improved performance in packaging development and packaging processes.

Design Verification Testing and Shelf Life Studies
• Establishes confidence in minimum seal strengths based on data.

Packaging Process Qualifications
• Generated confidence in sealing ranges to ensure process has established lower limits outside OQ low parameters.
Acceptance Criteria – Industry Standards?

ISO 11607-1, 4.3:
– The sampling plans used for selection and testing of packaging systems shall be applicable to packaging systems being evaluated. Sampling plans shall be based upon statistically valid rationale.
“Industry Standards”

• 30 variable, 60 attribute
• “This is what we always used”

Acceptance Criteria – Sample Size

Sample sizes must:

• Be risk based (RPN).

• Comply with risk acceptable to the organization.

• Be document and statistically justified.

☑ Note: The FDA has recently recommended a 30/60 sample size, but justification is still required.
Audit/Complaint Processes

Audit/Complaint Processes – Corrective Action Improvement

Plan – Internal Packaging Audit
- Conduct comprehensive audit

Do – Analyze and sort data
- Pareto results to focus resources

Check – implement solutions
- Address major opportunities for improvement

Act – Monitor Improvements
- Evaluate performance for quality/complaint improvements.
Trending in Medical Device Packaging

Risk Mitigation

Test Method Recognized

ISTA Procedures 3A, 3B and 3E Recognized by FDA as Consensus Standards

For many years ISTA test procedures have been referenced in ISO 11607 which serves as the principal guidance document for validating terminally sterilized medical device packaging systems. Recently ISTA took the steps required to also have ISTA 3A, 3B, and 3E directly recognized by the FDA. With the FDA’s announcement in Vol. 81, No. 183 of the Federal Register on Wednesday, September 21, 2016 ISTA 3A, 3B, and 3E were officially recognized by the FDA as consensus standards and are now present on the FDA’s CDRH Recognized Consensus Standards Database.

ISTA Distributing Confidence, Worldwide.

1400 Abbott Road, Suite 160, East Lansing, MI 48823 USA 517.333.3437
Combination Products

- Fast growing segment within Medical Device - $16.5 billion in 2014 w/ 12% yearly growth expected.
- Leads to expansion of technical and regulatory requirements of packaging systems.
- Example: Drug Eluting Stent – drug coated medical device to block cell proliferation.

Combination Products

**FDA Structure and Organization – Medical Devices**
Healthcare Providers

Historically
- Sterile and functional over the shelf life.

Trending Now
- User needs and user interface, functionality, human factors, ergonomics, and user validations.

Risk Mitigation – ALARP VS. As Low as Reasonable

D.8 of ISO 14971, 3.4
- ALARP contains an element of economic consideration
- Essential Requirements require risks to be reduced as “far as possible” without room for economic considerations.

If technologies or process improvements exist to mitigate risks further, they must be implemented.

Risks introduced by the implementation of risk mitigations also need to be assessed.

Risk management is a life cycle process – future technologies or solutions that become available are required to lower risks.
## Technology
### In-Cell Vision Inspection

**Situation**
Vison inspection for correct part is not effective if orders mix before sealing

**Solution**
Vision inspection located at each package sealer
- Eliminate mixups between inspection and sealing
- 100% correct part
- Continuous flow

**Benefits**
- Reduce recalls from part mix-ups
- More error-prevention tool add-ons are possible:
  - Pouch seal detection
  - Check-weighing
  - Calibration monitoring
  - Set point confirmation

![Screw Vision System Optimized for In-Cell Technology](image)

## Technology
### 100% Inspection for Missing Pouch Seals

**Situation**
Unsealed pouches will cause field action.

**Solution**
100% vision inspection for pouch seal presence
- Detects missing seal
- Detects mis-oriented seal
- Logs & reports results

**Benefits**
- Eliminate dependence on operator inspections
- Reduce complaints and recalls

![Unsealed Pouches Vision Using Enhanced Lighting](image)
Consumer Trends in Corrugated Industry and Packaging Design

Srin Rajagopal¹ and Alex Beviere²

Abstract: Packaging plays a key role in ensuring product quality and promoting its safe and effective use. International Paper manufactures and ships containerboard and corrugated packaging for food and beverage, consumer and industrial goods, and distribution and ecommerce across the globe. Commercial world that we play in is changing: behaviors, demography, etc. Corrugating industry is also changing to adapt to these changing preferences with new and improved substrates and innovative design process.

Following topics will be discussed

• Overview of International Paper
• Sustainability
• Market Trends
• Consumer Trends
• Industry adapting to changing trends
• Packaging Design

Keywords: Consumer Packaging Trends, Corrugate Market Trends, Industrial Packaging, Sustainability, Packaging Design

Presenters:

Srin Rajagopal - Dr. Rajagopal has 30 years’ experience in Nuclear Medicine, Atomic Energy Research, Cellulose Chemistry, Dissolving pulp and Industrial Packaging in Canada and USA. Srin is now responsible for managing the product enhancement process for the Containerboard product lines (International Paper- Industrial Packaging Sector) and serve as a central technical resource for Containerboard’s sales and customer support groups. In addition, Srin also leads Business Intelligence initiatives to deliver insight to business information for senior leaders in the company. Srin began his career in nuclear medicine as a post-doctoral fellow at the Montreal Neurological Institute and Hospital, McGill University, Canada. He later worked in Atomic Energy Canada Limited (AECL) unraveling radiation applications and supporting sale of Electron Accelerators. In 1997, Srin joined Natchez Mill, International Paper, serving various roles in customer product quality, technical marketing, IT and Process Control. Later, he worked in Corporate IT as Manufacturing IT Manager for IPG mills until 2012.

Alex Bevier - Alex Bevier has over 25 years’ experience in the corrugated packaging industry with an emphasis on manufacturing processes and product design. Alex is the Design Services Manager for the South and currently manages International Paper’s design resources in the South East US covering 11 states as well as leading the efforts at IP’s Memphis Customer Commitment Center to meet customer needs related to structural and graphic design. He is also intimately involved in innovation related to die cutting technology and process improvement.

¹ International Paper, Srin.Rajagopal@ipaper.com
² International Paper, alex.bevier@IPAPER.com
**IP Makes Things That Matter**

**INDUSTRIAL PACKAGING**
IP manufactures and ships containerboard and corrugated packaging for food and beverage, consumer and industrial goods, and distribution and eCommerce across the globe.

- 65% of total revenue
- 22% of total revenue

**CONSUMER PACKAGING**
IP’s global coated paperboard business is used in a wide variety of packaging and foodservice applications including cups, food containers and consumer goods.

- 13% of total revenue

**PAPER AND PULP**
IP produces uncoated papers that help consumers communicate, advertise, and educate across the world. The pulp business produces fluff pulp for absorbent hygiene products that consumers rely on.
International Paper – Industrial Packaging

- IP produces over 100 million boxes per day
- CTA has over 10,000 customers
- Containerboard ships to 71 countries, over 1/3 of the World
- IP's annual containerboard production would circle the globe 600 times
- 1 in 3 boxes in the US is manufactured by IP

CTA
$10.2B Rev.
9.3 MM Tons

IPG
$11.9B Rev.
12.4 MM Tons

Our Industrial Packaging Offer

- Containerboard: Linerboard and medium to make corrugated packaging and other packaging products
- Corrugated Packaging: Boxes and sheets used to ship, store, and sell various products.
- Bulk Packaging: Bulk bins and containers for liquids, dry goods, and bulk foods
- Retail Display: Point-of-purchase displays to drive sales in retail
- Paper Bag: Bags and sacks for grocery, fast food, and other retail outlets
- Recycling: Recover paper and packaging to make new paper products.
Our Industrial Packaging Offer

Operations in more than 24 Countries

People employed 58,000 Worldwide

Industrial Packaging 18 Million Tons Sold

Industrial Packaging $14.5 Billion Net Sales

Sustainability Leader

International Paper's 2020 Sustainability Goals

Energy Efficiency 15% improvement of energy efficiency in purchased energy use.

Green House Gas Emissions 20% absolute reduction in global GHG emissions associated with the production of our products.

Air Emissions 10% reduction in criteria pollutant emissions by aligning with our Energy Efficiency Initiatives.

Water Quality 15% reduction in mill wastewater discharges of oxygen depleting substances (BOD, COD) to receiving streams.

Solid Waste 15% increase in the recovery of Old Corrugated Containers (OCC) by exploring new sources and diverting useable fiber from the landfill.
Healthcare Packaging Trends

- Packaging plays a key role in ensuring product quality and promoting its safe and effective use.
- Traditionally, the pharmaceutical and medical device tech markets have been very well defined. However, these 2 markets are converging.
- According to Freedonia, drug delivery is "the fastest expanding group of disposable medical supplies," expected to reach $13.4 billion in 2018 in the United States; thanks to "minimally invasive delivery of parenteral medicines, inhalation therapies," and more.
- The challenge to engineers in both industries is to develop user-friendly packaging and drug-delivery devices, while addressing the need to lower the overall cost of healthcare.

Healthcare Packaging Trends - Pharma

- US is the largest pharmaceutical market in the world, ~45% of global sales in 2015 or $413 B, which grew 12% in 2014.

<table>
<thead>
<tr>
<th>Country</th>
<th>Market share</th>
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<tbody>
<tr>
<td>United States</td>
<td>36.1%</td>
</tr>
<tr>
<td>China</td>
<td>10.3%</td>
</tr>
<tr>
<td>Japan</td>
<td>8.3%</td>
</tr>
<tr>
<td>Germany</td>
<td>4.6%</td>
</tr>
<tr>
<td>France</td>
<td>3.6%</td>
</tr>
<tr>
<td>Brazil</td>
<td>3%</td>
</tr>
<tr>
<td>Italy</td>
<td>2.7%</td>
</tr>
<tr>
<td>Great Britain</td>
<td>2.6%</td>
</tr>
<tr>
<td>Spain</td>
<td>2.6%</td>
</tr>
<tr>
<td>Canada</td>
<td>2%</td>
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US consumers spent $425 Billion on medicines.

Top ten pharma. Companies are...

<table>
<thead>
<tr>
<th>Company</th>
<th>Revenue in billion U.S. dollars</th>
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<tbody>
<tr>
<td>Johnson &amp; Johnson</td>
<td>49.6</td>
</tr>
<tr>
<td>Pfizer</td>
<td>42.2</td>
</tr>
<tr>
<td>Merck</td>
<td>24.9</td>
</tr>
<tr>
<td>Gilead Sciences</td>
<td>20.2</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>20.1</td>
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<tr>
<td>Amgen</td>
<td>19.6</td>
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<tr>
<td>Abbvie</td>
<td>19.5</td>
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<tr>
<td>Eli Lilly</td>
<td>15.9</td>
</tr>
<tr>
<td>Bristol Myers Squibb</td>
<td>13.1</td>
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Source: Statista Dossier
Healthcare Technology Trends

- US medical technology companies spent $11.4B in research and development projects, compared to $2.9B in Europe

Medical instrument companies in the US earned $96B in revenue in 2014.

The World is Changing

Consumers are Changing

Companies are Adapting

How is International Paper Responding?

Source: Statista Dossier
Consumer Trends Drive Segment Performance

Retailers and CPGs are Pursuing Millennials

Largest Population Segment

BY 2030
MILLION
OUT NUMBER
BOOMERS
BY 22 MILLION

Entering Peak Spending Years

Consumer Lifecycle

HEALTHY
• Less Informed
• Low Fat = Healthy
• Less Options
• Quick Access to Nutritional Info
• Fresh Foods = Healthy
• Many Health Oriented Startups

CONVENIENCE
• Brick & Mortar – Only Option
• Try before Buy

NATURAL
• Artificial Preservatives
• GMOS/Antibiotics
• Fewer Ingredients
• Organic/Natural

10/29/2016
**Fresh Foods Driving Growth at Grocery**

- **Sales of fresh foods are up**
- **Shoppers abandoning center aisles**
- Now shopping the *perimeter* of the store

**Store Perimeter**
- Fresh Foods

**Center Aisles**
- Processed Foods

- **Sales of processed foods are down**

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**How are Major CPGs Adapting?**

- **CPGs are attempting to reposition their brands**

  - **If you Can’t Beat Them – Buy Them**
    - Aggressive acquisitions of fast growing food brands
    - 30+ food related M&As in past two years
    - Nearly half were natural /organic foods companies

  - **Kraft-Heinz**
    - Remove artificial colors and preservatives
  - **Campbell’s**
    - Remove all artificial ingredients by 2015
  - **Nestle**
    - Remove artificial flavors & reduce salt
  - **General Mills**
    - Eliminate artificial additives
  - **ConAgra Foods**
    - Create simpler, more natural frozen meals
How is Packaging Industry Adapting?

• Light weighting of boxes
• Coated corrugated boxes
• Wet strength corrugated boxes

Corrugated Market Trends

Sustainable Packaging
• Wax alternatives
• Recycle content
• Lightweight liners

Right Size Box
• Smaller box size
• Smaller order quantities

Premium Packaging
• Inside Print
• Enhanced graphics
• Retail displays
Driven by purpose

- Good packaging design is always a driven by clearly stated objectives
  - Protect the product better
  - Sell more product
  - Reduce material
  - Create brand recognition
  - Handle more easily
  - Optimize the supply chain
What boxes do

- **Contain** - provides for an efficient shape for bulk or loose products to facilitate handling and distribution
- **Protect** - provides isolation from external forces during handling and transportation
- **Store** - provides for the structure, stability and strength for efficient long term storage
- **Inform** - provides space for the application of distribution and inventory control information
- **Provide Recognition** - provides efficient means for display and product focus
- **Advertising/Marketing Tool** - provides billboard for shelf/pallet product promotion display

Understand the product

- Is the product's construction fragile or sturdy?
- Is the product sensitive in function?
- Does the product require certain conditions?
- How heavy is the product?
- How large is the product?
- Does the product have surfaces that cannot handle abrasion?
- Is the product time sensitive?
- What is the cost of package failure?
Understand the packing process

- Is packing part of the assembly process?
- Automated
- Manual
- Continuous
- Stop motion
- On or off line

Understand storage and shipping

- Where will the product be stored?
- How long will it be stored?
- What are the conditions in both temperature and moisture?
- How will the conditions change over the lifetime
Packaging Development Process

- **Package Development Stage**
- **Laboratory Testing** (when required)
- **Field Trials** (when required)
- **Production**

These four phases of the design process reflect the International Paper approach to developing a consistent container designed to meet the needs of each customer and each environment in which that container functions.

Development Process For New Products Launches

1. **Gather information and data points**
   - Production line, supply chain, marketing and packing engineers, product characteristics

2. **Develop concepts**
   - Blend design preferences with performance needs

3. **Validate performance of concepts**
   - Establish testing protocol and conduct testing

4. **Present concepts, samples and pricing**
   - Packaging prices, machinery cost if applicable, and performance indexes

5. **Conduct trials on chosen concept(s)**
   - Production made packaging, validate line viability, validate performance

6. **Implementation of design**
   - Packaging to machine supplier, installation of equipment, final art and package production
1. Package Development Stage
- Information (Goals, Parameters) – International Paper: Project Request Form
- Engineering (Package Development) – “CAPE”, “Boxcomp, Impact”
- Preliminary Prototypes
- Evaluation & Customer Approvals – Project Goals Assessment

2. Laboratory Testing (when required)
- Samples – Cad Table, Handmade, Simulated Production
- Determine Contribution of Product/Properties
- Standard TAPPI Testing Protocol
- Evaluation & Customer Approvals – Goals Assessment

3. Field Trials (when required)
- Production Line Evaluation
- Distribution System Evaluation
- Samples – Controll Trials, Pack Outs, Unit Loads Shipped
- Static Stacking
- Evaluation & Customer Approvals – Goals Assessment

4. Production
- Performance Feedback
- Evaluation & Customer Approvals – Goals Assessment

These four phases of the design process reflect the International Paper approach to developing a consistent container designed to meet the needs of each customer and each environment in which that container functions.

Each phase is a distinct and essential element in achieving the optimum design. The participatory process involving the customer provides the foundation upon which the developmental process is based. The International Paper Design Manager, who understands materials and style, applies his knowledge with customer input to develop potential options. Working together through the developmental process, exploring options and validating assumptions allow the customer and Designer to arrive at conclusions and a design having the highest probability of satisfying the customer needs at a reasonable cost. From this process a design is agreed upon, produced and placed in the production/distribution environment for further evaluation.

Any design is based upon the best information available to all parties at the time of development. Environments, needs and products all affect the performance of the container and constantly change. The need for review and evaluation continues indefinitely.

Understand Innovation

To improve the human condition in an unexpected way
Reveel

- On the fly
- Customizable
- Unique identifier at single pack level

Reveel
**Clima Shield**

- Moisture control
- Multiple levels of protection
- Recyclable

---

**Cabrio Case**

Efficient to retail

- Minimize material
- Pack efficiently
- Ship securely
- Display easily
- Don’t interfere with shopping
**Enhancing the process**

- Process devices to help with sterilization

**Interior fitments**

- Stabilize
  - Improve product protection
  - Aid in assembly
  - Provide mechanism for future storage
Questions?

Thank You!
Funding the Commercialization of Innovation:
The ins and outs of investment financing

Allan Daisley

Abstract: This talk explores how investment financing is used to help commercialize innovation. It covers the stages of funding, from early "friends and family" funding, all the way to full on institutional (venture capital) investment. It highlights the differences between the various types of funding and when to use each one.

Keywords: Commercialization; Investment Financing; Venture Capital

Presenter:

Allan Daisley – Allan Daisley is director of entrepreneurship and sustainability at Memphis Bioworks and co-founder/president of the ZeroTo510 Medical Device Accelerator, an innovative, first-of-its-kind entrepreneurship program that helps entrepreneurs launch new medical technology companies, navigate the startup process and deliver their products to market. ZeroTo510 uses a methodology that combines an intensive mentorship-driven, cohort-based program with a seed investment in each company.

Allan previously founded his own economic development consultancy and managed a business incubator program focused on leveraging entrepreneurship and technology as key drivers of sustainable economic development. Prior to that spent time in senior strategy and marketing roles at IBM, as a consultant at Accenture, and as an entrepreneur in two start-up ventures. Allan has an MBA from Duke University and a Bachelor of Science in Computer Engineering from the Georgia Institute of Technology.

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FUNDING THE COMMERCIALIZATION OF INNOVATION

The Ins and Outs of Investment Financing

Allan Daisley
President
ZeroTo510 Medical Device Accelerator
allan@zeroto510.com

USING OTHER PEOPLE’S MONEY!
AGENDA

- The Start Up Process
- Funding Phases and Types of Investor
- Getting Investment
- Pitfalls & Lessons Learned
- Parting Thoughts
- Q&A

ABOUT ME

Allan Daisley
President, ZeroTo510
Director of Entrepreneurship, Memphis Bioworks
INTRODUCTION

Invention is part of the American Dream
- Taking a product to market can be expensive
  - People, equipment, manufacturing, marketing…
- If not wealthy, Need to raise money
- What to do?

FIND PEOPLE WITH MONEY
...AND USE THEIRS!
FUNDING PHASES

- Seed
- Early/1st Stage
- Growth/2nd Stage
- Expansion/3rd Stage
- Mezzanine/“Bridge”
- IPO

Friends Family
Super Angels
Angels
Invest. Banks
Private Equity
Venture Capitalists

SEED STAGE

- Getting the idea off the napkin
- Relatively small amounts of cash (<$50K)
- Large uncertainty (does it work?)
- Source: Self, Grants, Loans, Family, friends, Angels
- Can be dilutive or non-dilutive
EARLY STAGE

- Getting to proof of concept
- Find product/market fit
- Larger investment than “seed” ($50K-$750K)
- Source: Angel groups, Super Angels, Early Stage VCs

GROWTH STAGE

- Acquiring customers and building scale
- Filling critical team roles
- Selling into new accounts and building revenue
- Larger investment ($1MM-$5MM)
- Source: Angel groups, Super Angels, VCs
EXPANSION STAGE

- Expansion to new territories
- Optimizing manufacturing for scale
- Achieving rapid sales growth
- Larger investment ($5MM-$15MM+)
- Source: VCs

VENTURE CAPITAL

- Can be early or much later stage
- Firms Comprised of General and Limited Partners
- Corporate entity that raises funds from institutions and wealthy individuals ("Institutional")
- Typically invests $100K-several million for equity stake
- Wants significant stake to share in rewards
- A fund lasts 5-7 years
A LOOK INTO THE MIND OF THE INVESTOR

- Charged with making better than average returns on a fund
- Strategy: Each deal should have the potential to make back a multiple of $$ invested
- Play the numbers (3/10)
- Take some control in the company (via board seat)
- Goal is some liquidity event to return capital
  - Sale or IPO

WHAT IS SUITABLE FOR VC INVESTMENT?

- High growth potential company (>3x return)
- Already has Proof of Concept; preferably customers too
- Big market, scalable model
- High barriers to entry
- Great team!
THE PATH TO INVESTMENT

TERM SHEET

- Document laying out the proposed terms of the investment
- Shares issued and price
- Company valuation (pre/post money)
- Types of shares issued and preferential treatment
- Board seats requested
- Protocol in case of Liquidation
- Etc.
USE OPM WISELY!

- VC sounds sexy but it is not always the right thing
- The most successful companies choose the right funding instrument for their business type and phase
- Try to get as much non-dilutive funding as possible
- Speed is critical: you can make mistakes and recover while there is still money left

THANK YOU!

Allan Daisley
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ANGEL INVESTOR

- Very Early Stage
- Wealthy Individual Gambling on a Solid Return
- Usually Invests $5K to $150,000 for Equity
- Tremendous Focus on the Entrepreneur/Team
- Usually Has Special Domain Knowledge
- Wants to Invest in What He/She Knows
- Wants a Product that is Defensible in the Market (Patent)

VALUATION

- What your company is worth
- Very subjective in early stage companies
- Always a difference between your valuation and the investor’s
- Pre-Money vs. Post-Money Valuation
- $20K/80K (pre) is different fraction than 20K/100 (pre)
ISTA Thermal Laboratory Certification

M. Sean June, Ph.D.

Abstract: The International Safe Transit Association offers certification for thermal laboratories, to enable ISTA package performance testing. It is the goal of CBU’s engineering department to build an ISTA certified thermal laboratory. With a thriving biomedical industry and the home of global shipping giant, Fed-Ex, Memphis is an obvious choice for an ISTA-certified thermal laboratory. This would also be a great compliment to our existing ISTA-certified packaging laboratory. CBU currently has the expertise, and is adding facility space to accommodate this new laboratory. This presentation discusses the need for this project, the existing infrastructure and expertise, what is needed to move forward, and our plans to address these needs.

Keywords: International Safe Transit Association (ISTA), Thermal Testing Laboratories, Thermal Testing, Packaging

Presenter:

Dr. M. Sean June is an assistant professor in the Department of Engineering at Christian Brothers University, in Memphis, Tennessee. Prior to his position at CBU, Dr. June was an assistant professor at Western Carolina University, in Cullowhee NC, and a 13-year veteran of IBM prior to WCU. He earned bachelor’s degrees from both the State University College at Fredonia NY (Biology), and the Rochester Institute of Technology (Mechanical Engineering), a master’s degree from the Rochester Institute of Technology (M.E.), and a PhD from North Carolina State University (M.E.). His research interests include electro-hydrodynamic flow, enhancement of heat transfer and propulsion. Dr. June can be reached at mjune@CBU.edu
Plans for an ISTA Thermal Laboratory at CBU

M Sean June

October 28, 2016

Meeting of the CBU Healthcare Packaging Consortium

Presentation/Discussion Outline

• Introduction
  • Experience
  • Qualification
• ISTA Thermal Laboratory
• Local Need
• Benefit
• Plan
• What are your needs?
Introduction

• New professor at CBU as of July
  • Mechanical Engineering
• Previously at Western Carolina University, Cullowhee, NC
  • Mechanical Engineering/ Mechanical Engineering Technology
  • Developed BSE curriculum, specifically Fluids, Heat Transfer and Thermodynamics classes and laboratories
  • Developed Fluid Dynamics, Heat Transfer and Thermodynamics for MSET program
  • Developed Thermodynamics/Heat Transfer course for ET program
  • Set up first thermo-fluidics research laboratory

Introduction

• Prior to WCU, Industry/Adjunct work
  • Thermoelectric Refrigeration Startup
  • IBM
  • Environmental Laboratory
  • NCSU, OCCC, RIT

• Consulting
  • Patents and Patent Policy
    • Named on over 25 US Patents
    • IBM Master Inventor, Patent Review Board (RTP)
    • Pursuing USPTO Registration (“Patent Bar”)
Introduction

• Research
  • Electro-hydrodynamics
    • Air moving devices
    • Propulsion
    • Cooling
    • Combustion
    • Air Filtration
  • Education
    • Thermodynamics/Thermo-fluidics
  • Other!
Introduction
Introduction

• In addition to teaching at CBU, I will be building and certifying an ISTA Thermal Lab

ISTA Thermal Laboratory

• What is an ISTA Thermal Laboratory?
  • The International Safe Transit Association certifies thermal laboratories which
    • Follow ISTA test protocols
    • Follow ISTA equipment calibration protocols
    • Follow ISTA sample chain of custody requirements
    • Follow ISTA data storage and archive procedures
    • Employ at least one level 2 certified technician
  • ISTA supplies a thermal and altitude profile to simulate the external conditions of a package in transit.
    • The laboratory would, among other things, test the temperature inside the package.
ISTA Thermal Laboratory, Local Need

• Why an ISTA Thermal Laboratory needed at CBU?
  • Currently, only 4 ISTA-certified thermal transport labs in the world
  • There is 1 in California, 2 in New Jersey, and 1 in Ohio
  • The west, northeast, and great-lakes region are covered, but none in the Southern US
  • Proximity to Fed-Ex (The Shipper)
  • Proximity to International Paper (The Supplier)
  • Thriving healthcare manufacturing base in Memphis, with a need for temperature controlled or regulated packaging (The Customer)
  • Other existing industries and future industries (Potential Customers)
  • Can serve industries closer to Memphis than NJ, Ohio, and Ca
ISTA Thermal Laboratory, Benefit

• How does an ISTA Thermal Laboratory benefit us?
  • Members of the consortium will have access to thermal testing and expertise that you likely won’t have in-house
  • Bio-related startups will have access to equipment and expertise without the need to grow it in-house
  • This will help differentiate CBU from other institutions
    • Certification opportunities for graduates
    • Undergraduate research opportunities for students
    • Real-world experience, internship-type opportunities for students
    • Establish CBU as a center of competency for this kind of work
    • Opportunities for invention/entrepreneurship for students and faculty

ISTA Thermal Laboratory, Plan

• How do we accomplish this?
  • Seek level 1 and level 2 certification for technician (me).
  • Acquire ISTA 7E Thermal Profiles and ISTA standard 20 ($10k).
  • Acquire Equipment
    • Environmental Chamber ($-270k)
    • Calibrate-able data acquisition system ($15k estimated)
    • Data collection and storage IT infrastructure ($2k)
    • Consumables
  • Space
Certified Thermal Transport Lab

The 7E Thermal Profiles are the only standard Industry-defined global thermal profiles available for performance testing of ISCs in accordance with ISTA Standard 20. The standard includes heat and cold profiles developed from data gathered in real world transport. All the lane data and protocols on how data was gathered are available for purchase through ISTA. Price: $10,000

Standard 20 is a design and qualification process for insulated shipping containers. It is a comprehensive set of requirements to achieve a certified package according to ISTA 7E. The companion document, STN-0014, details specifics of audit requirements for thermal transport lab certification. Price: $10,000

Each lab seeking to become an ISTA Certified Thermal Transport Lab must make application to ISTA. Price: $500

Each lab seeking certification based on ISTA 7E shall have a Certified Thermal Professional Level I. Lab personnel can achieve Level I certification by passing an online test. Each lab shall have at least one CTP Level I. Price: $295 - $425

Each lab seeking certification based on ISTA 7E shall have a Certified Thermal Professional Level II. Level II status is a two step process, including an online "pre-test" and an in-person training session with a Certified ISTA Thermal Transport Auditor. The CTP Level I and II can be the same person. Price: $1,295 - $450

Each lab seeking to become an ISTA Certified Thermal Transport Lab must then apply for an audit. Submission of a pre-audit checklist is required to schedule an audit. After successful review, an on-site audit is scheduled. Price: No Charge
Open Discussion. Your Needs?

- R&D requiring thermal capability?
- Existing product or product packaging testing?
- Other?
Packaging R&D Projects @ CBU

Siripong Malasri

Abstract: Results of two current R&D projects at CBU will be presented. These projects are:

- **Humidity Factor for Corrugated Box Compression Strength:** In this project, humidity factor for corrugated box compression strength was determined from an ISTA publication, box compression test, and edge crush test. These factors are found to be comparable and produce far better results than the basic McGee Formula at high humidity conditions.

- **CBU Temperature/Humidity Chamber 2.0:** In this project, a chamber was built with two-inch thick Styrofoam. Temperature and humidity were controlled by a home-grade space heater and humidifier. A temperature/humidity data logger was placed in the chamber to measure the actual condition. A calibration software/spreadsheet is being developed for the chamber using an artificial neural network model.

Keywords: Corrugated box compression strength; Humidity factor; Temperature chamber; Humidity chamber

Presenter:

Siripong Malasri, PhD – Dr. Malasri is currently Dean of Engineering and Director of the Healthcare Packaging Consortium at Christian Brothers University. He is an ISTA CPLP (Professional Level) and a registered professional engineer in Tennessee. His research interests include artificial intelligence applications and packaging.

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Packaging R&D Projects @ CBU

Siripong Malasri
Healthcare Packaging Consortium
Christian Brothers University
650 East Parkway South, Memphis, TN 38104, USA
pong@cbu.edu

Presentation Outline

- Humidity Factor for Corrugated Box Compression Strength
  By Sesha Mounika Kota, Radhika Suryadevara, and Pong Malasri

- CBU Temperature/Humidity Chamber 2.0
  By Erica Thomas, Pong Malasri, Bob Moats, and Dustin Schrecongost

- Other Projects
Humidity Factor for Corrugated Box Compression Strength

Methodology

• ISTA Certified Packaging Lab Technician Exam Preparation Material
• Compression of Corrugated Boxes at 73F and RH from 50% to 90%
• ECT Test at 73F and RH from 50% to 90%
• Average of the three above

ISTA CPLP Technician Exam Material
Humidity Factor = \frac{BCT}{100}

<table>
<thead>
<tr>
<th>RH (%)</th>
<th>BCT (%)</th>
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<tbody>
<tr>
<td>50</td>
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<td>55</td>
<td>96</td>
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<td>90</td>
<td>48</td>
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<td>95</td>
<td>29</td>
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</tbody>
</table>

Box Compression

C Flute Single Wall Boxes
200 psi Burst Strength

Five sizes:
- 4X4X12
- 5X5X3
- 8X6X4
- 12X10X8
- 12X12X8

Test Conditions
- Temp = 73F
- RH = 50%, 55%, 60%, ..., 90%
\[ y = -0.0003x^2 + 0.0319x + 0.1853 \]

\[ R^2 = 0.979 \]

**Average Box Humidity Factor**

**Edge Crush Test (ECT)**

2”X2” specimens from the following box sizes:

- 4X4X12
- 5X5X3
- 8X6X4
- 12X10X8
- 12X12X8

**Test Conditions**

- Temp = 73F
- RH = 50%, 55%, 60%, ..., 90%


\[ y = -0.0002x^2 + 0.0124x + 0.7845 \]
\[ R^2 = 0.9613 \]

**Average ECT Humidity Factor**

![Graph showing the relationship between RH (%) and Humidity Factor]

**Average of ISTA, Box, and ECT Methods**

<table>
<thead>
<tr>
<th>RH %</th>
<th>Humidity Factor</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>ISTA</td>
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<tr>
<td>50</td>
<td>1</td>
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<tr>
<td>55</td>
<td>0.96</td>
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<td>85</td>
<td>0.57</td>
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<tr>
<td>90</td>
<td>0.46</td>
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</tbody>
</table>
$y = -0.0002x^2 + 0.0211x + 0.5302$

$R^2 = 0.9906$

<table>
<thead>
<tr>
<th>Temp</th>
<th>Humidity</th>
<th>McKee</th>
<th>ISTA</th>
<th>BOX</th>
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<th>AVG</th>
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</table>

\[ Min = 12 \quad 14 \quad 12 \quad 14 \quad 14 \]

\[ Max = 90 \quad 25 \quad 21 \quad 28 \quad 24 \]

\[ Avg = 30 \quad 16 \quad 15 \quad 17 \quad 16 \]

McKee Formula

\[ BCT = 5.876 \times ECT \times \sqrt{U \times d} \]
CBU Temperature/Humidity Chamber 2.0

← CSZ Temperature & Humidity Chamber Model ZP-32 (-49F to +374F, 10% to 98% RH, 38”x38”x38” chamber size)

CBU Chamber 1.0 →
Measuring Chamber Insulation Material for Water Absorption

73F, 50% RH

Calibration Chart for RH

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<thead>
<tr>
<th>Set of Desired RH (%)</th>
<th>Actual RH (%)</th>
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<tr>
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</tbody>
</table>

Calibration Charts:
- 70°F: $y = 0.8308x + 5.7125$ ($R^2 = 0.9401$)
- 80°F: $y = 0.8175x + 7.7106$ ($R^2 = 0.975$)
- 75°F: $y = 0.8246x + 7.6235$ ($R^2 = 0.9420$)
- 70°F: $y = 0.8033x + 6.5108$ ($R^2 = 0.9983$)
- 85°F: $y = 0.8894x + 3.5799$ ($R^2 = 0.9701$)
Calibration Chart for Temperature

<table>
<thead>
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<th>Actual Data Logger Readings</th>
<th>Temp/F</th>
<th>RH/%</th>
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</tbody>
</table>

Temperatures: 60°F, 70°F, 80°F, 90°F, 100°F

Chamber Calibration Software

- All Data was entered into Neural Network for calibration
  - Desired Temp & RH
  - Actual Data Logger Readings
- Neural Network Generated an Algorithm & Produced a Calibration Chart in which:
  - The desired Temp & RH could be entered, and
  - The actual settings needed for the Space Heater & Humidifier would be generated.

Desired Temperature (F) | 80 | Input
Desired RH (%) | 55 | Input
Set Temperature (F) | 71.49398167 | Output
Set RH (%) | 53.54100772 | Output
Validating Neural Network Output Data

Trend line equations from the Temperature and RH Calibration Graphs were used to validate the Temperature and RH Output settings generated by the Neural Network.

Can Neural Network Generalize?
Other Projects

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