

## ***Summary Day 2: “Triple Bottom Line”***

Ø Environmentalism and sustainability are no longer “nice to haves” but are a business imperative.

– Not going green is not an option.

Ø Engaging with investors, employees and community is critical.

– Environmental – Social – Economic

Ø Understand your footprint, understand your real needs, understand the broader market place.

– Your waste may be someone’s input material

## ***Summary Day 2: “Benign by Design”***

Ø Benign by design goes hand-in-hand with quality by design.

– Requires creativity and innovative research

– New ways of thinking, new ways of teaching

Ø Is an industry coalition around secondary and tertiary packaging needed, or does one already exist?

Ø Is there a possibility to bring an ICH topic on green design and manufacturing?

## ***Summary Day 2:***

***“Climate change is here. Anticipate other changes”***

- Ø Changes similar to the CFC-HFA transition are coming!**
  - Get ahead of the curve and proactively change to green processes!
- Ø Health and environmental authorities need to communicate with each other.**
- Ø Need to leave the world livable and enjoyable for the subsequent generations**
- Ø Requires long-term thinking and assessment of impact**

## ***Summary Day 2:***

***“We are all in it together”***

- Ø Industry must work together with patient advocacy groups for the common ground**
  - Be practical and proactive re: patient issues
  - CFC-HFA Transition: Opportunity to take a similar communication approach as analog-to-digital TV transition
- Ø Terminology is important for patients and affects the way they handle medicines.**

## ***Summary Day 2:***

### ***“Risk Management is more than just FMEA”***

**Ø FMEA is more helpful later in the process**

- Has to be revisited and revised throughout product lifecycle

**Ø QbD can be applied practically to OINDPs**

- Breaking down complex systems and processes into subsystems and blocks makes it possible

**Ø “You can’t develop a process if you have a rubber ruler.”**

- QbD should apply to control strategy and analytical methods as well.

## ***Summary Day 2:***

### ***“Is it a drug? Or is it a device?”***

**Ø Devices and drugs are regulated differently but not mutually exclusively.**

- Opportunity for convergence and for learning from each other.

**Ø Communication between device and pharma companies must be a two-way street.**

- Mutual information sharing is the only way to ensure efficient design.

**Ø Risk assessment (and not a guidance) should drive the design and change control management.**