

# **Mitigating Business Risks: Proactive Environmental Compliance**

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## **Abstract:**

*AB SCIEX is a world leader in designing, manufacturing and marketing sophisticated analytical instruments and services that have and continue to contribute to the health and well-being of people around the world.*

*As these instruments are developed, every effort is made to ensure that the designs meet/exceed all regulatory and environmental legislative requirements applicable at the time these products are introduced into the marketplace.*

*This paper and presentation will provide an overview on how AB SCIEX has successfully implemented its product environmental compliance management program, tools and approaches enabling development teams to have "Design for Environment" solutions that check for material content information from any design view, and cross-references this data against multiple global regulations and directives.*

*Additional efficiencies in integrating Global Supply Chains and manufacturing operations will also be described, outlining key strategies for successfully ensuring AB SCIEX suppliers buy in and commit to our environmental program goals.*

*Today AB SCIEX fully understand and is committed to proactively addressing environmental concerns around waste, toxicity, and disposal of products and services on an ongoing basis within product development, manufacturing and field support operations around the world and at the same time ensuring that global environmental regulations do not impact its ability to ship products to current and future customers around the world.*

## Introduction:

Addressing environmental concerns associated with hazardous electronic waste continue to present many new challenges to manufacturers, consumers and legislative jurisdictions. As newer technologies arrive at an ever increasing rate, consumers continue discarding their obsolete products at ever increasing rates.

In order to meet these current and upcoming European and global environmental legislative challenges, AB SCIEX established a formal environmental compliance program in 2010 whose primary goal was to:

***Ensure That Product Environmental Compliance Related Legislation Around The World Did Not Adversely Affect AB SCIEX's Ability to Ship Existing and Newly Developed Analytical Instrumentation Solutions To Current And Future Global Customers and Markets.***

As new instruments are developed, every effort must be made to ensure that the designs meet/exceed all global regulatory and environmental legislative requirements applicable at the time these products are introduced into the marketplace.

How AB SCIEX was impacted by these ongoing legislative developments and what is being done to address them will be outlined in more detail within this paper.

## Background to Current Environmental Compliance Landscape:

The European Union today continues to lead the way in addressing many of the environmental concerns associated with specific hazardous substances.

In addition to the electronic waste problem, RoHS and REACH reflect contemporary research over the past 50 years in biological toxicology that acknowledges the long-term effects of low-level chemical exposure on populations. New testing today, through instruments such as ours, allows for the detection of much smaller concentrations of environmental toxins. Researchers are now able to associate these exposures with neurological, developmental, and reproductive changes and disorders.

This is a significant change in approach as in the past environmental laws were designed to address only the impact of large amounts of toxins that caused severe injury or death.

In parallel, environmental procurement policies are continuing to gain acceptance in government and commercial circles. Today, more and more buyers base their purchasing decisions not only on product performance and cost but also on which products are more environmentally friendly irrespective of them meeting any current applicable legislated environmental directives.

Organizations face a number of challenges in establishing their environmental compliance and sustainability programs as outlined in a 2011 Tech Clarity report and included here.

One of the benefits of establishing an environmental compliance program is that the supplier data gathered for compliance can be leveraged in many cases towards sustainability.

This allowed for additional efficiencies to be realized within the overall program in data gathering and processing, ensuring that products get designed compliant right from the start.



Companies who respond proactively to these evolving environmental requirements are positioning themselves for future success earlier by being ahead of the ever increasing legislative directives brought forth around the world.

As a result of these developments, today many other countries around the world are continuing to develop and enact “RoHS-like” legislation based on European Union’s directives.

Most legislation is similar to the ones introduced by the European Union but there are significant differences: The two general approaches applied are:

**Substance Restrictions:**

Like RoHS restrictions, the restricted substances must not be present beyond specified limits for it to be legal to sell and sometimes the requirements go beyond RoHS.

**Substance Marking:**

The product must be labeled to show the presence of certain substances although the sale of the product is still allowed.

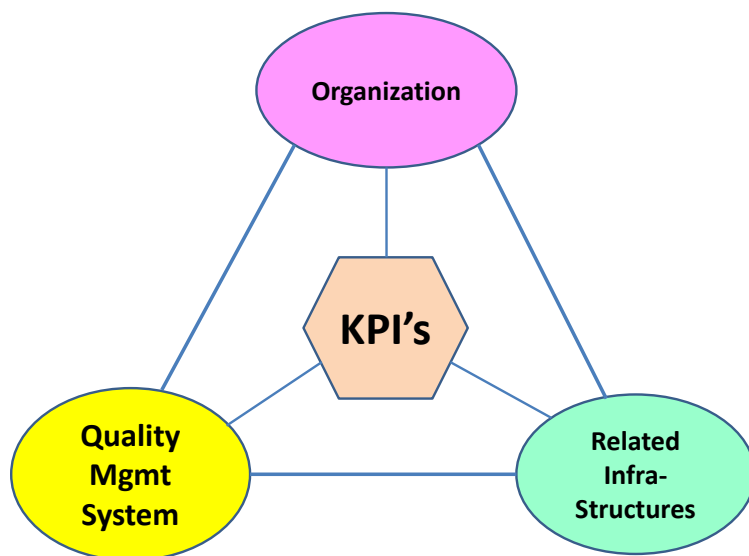
In summary, RoHS directives and similar global legislation were specifically enacted to significantly reduce human exposure to hazardous substances by restricting and/or eliminating their presence in the first place.

**Product Environmental Compliance Program at AB SCIEX:**

In response to these developments AB SCIEX established a formal Product Environmental Compliance, PEC program within the Quality Assurance department. The program mandate was to:

- Facilitate the implementation of a documented process across AB SCIEX that directs multidisciplinary development teams in updating existing products and designing new ones to meet environmental compliance requirements.
- Ensure that within the established process sufficient documented data is on file, can be easily retrieved and made available to provide an adequate level of proof of compliance in case of “country specific” audits.

These efforts were being spearheaded across AB SCIEX sites, and primarily where product design and manufacturing activities take place.



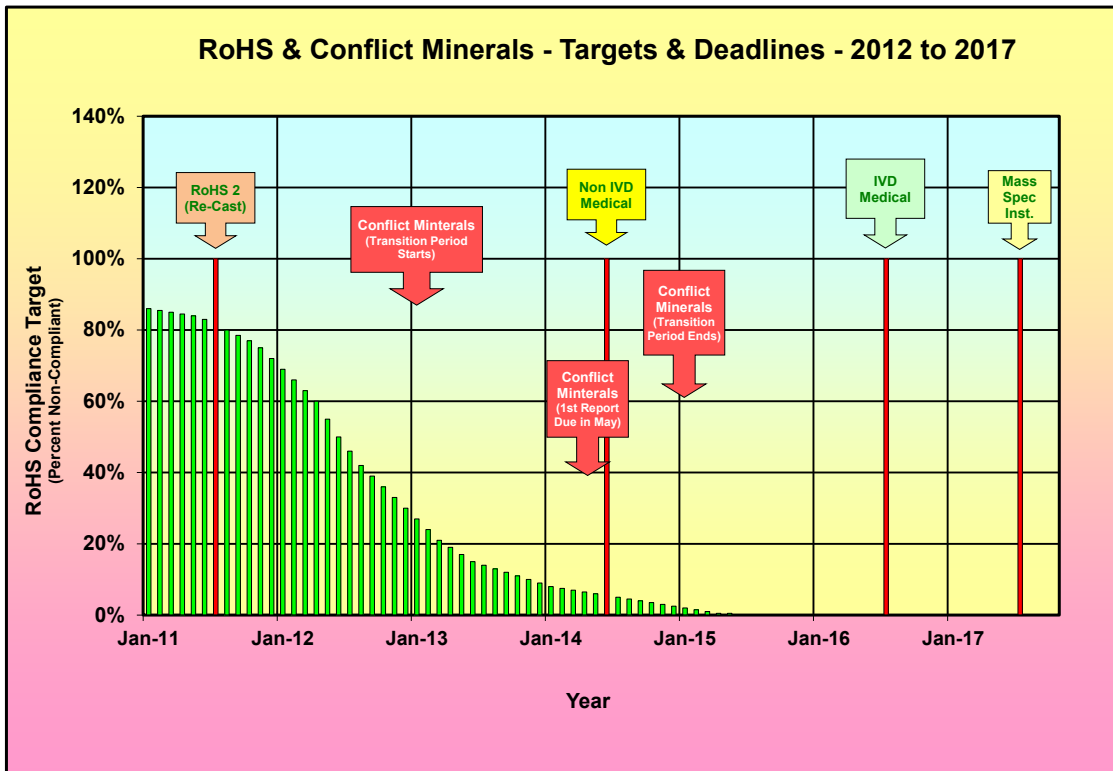
The figure to the left provides a pictorial presentation of the key environmental compliance building blocks at AB SCIEX.

There are a number of elements within each of these major areas and some will be described in more detail later in this paper.

Key Performance Indicators, KPI's, provide a formal way of tracking progress during various implementation phases of the program, while at the same time keeping senior management informed on progress towards completion.

The deadline for RoHS compliance for instruments such as ours, originally set to take effect in 2012, was extended due to global manufacturers of specific health and safety critical products requiring additional time to adequately mitigate reliability concerns around lead free soldering processes.

The table below provides a partial overview of the RoHS and Conflict Minerals targets and deadlines AB SCIEX has to achieve.

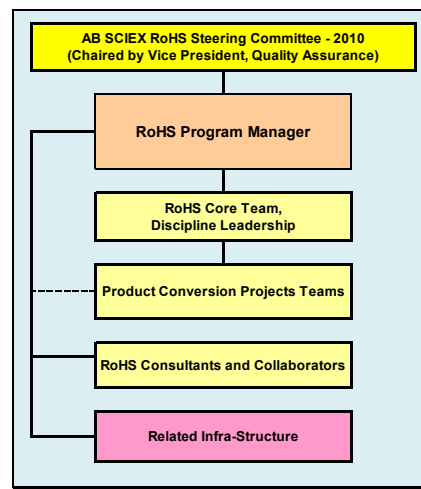


## Organizational:

It is of utmost importance that senior management clearly understands the nature of current and evolving environmental regulatory landscape and the potential risks to their business in cases of non-compliance.

Clear accountabilities within an organization must be established in order for the program to be successful.

The figure on the left provides an overview on how AB SCIEX was organized to move their program forward.

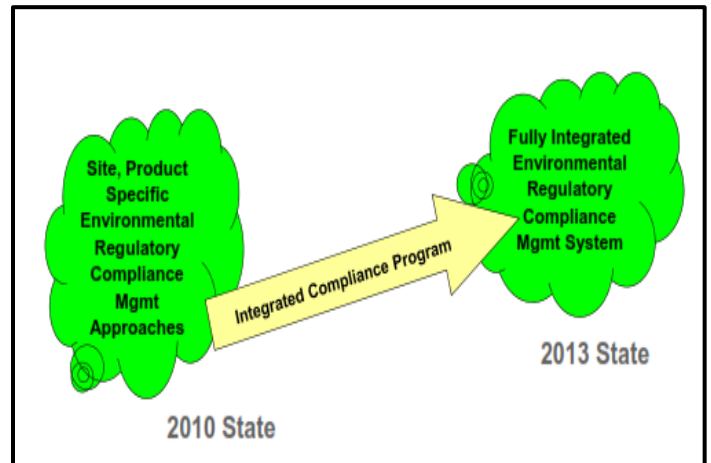


## PEC Related Infra-Structures:

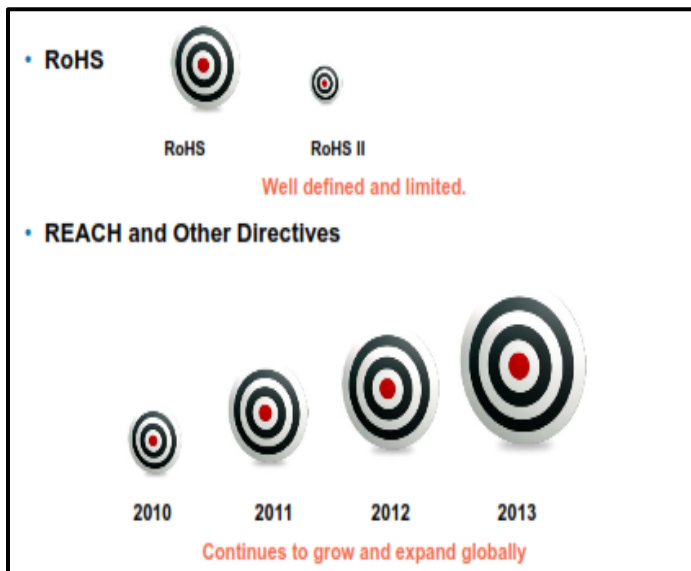
### **System Based Approach:**

At AB SCIEX, early on, a decision was made to build all of the related environmental compliance program infra-structures around a system based approach that is most suitable for an organization such as ours.

The key advantages in taking this approach were that it allowed AB SCIEX to integrate environmental compliance as part of the company's enterprise level processes and tool sets.



Although this approach requires a significant level of initial effort, the long term advantages are that it sets up the infra-structures to drive environmental compliance from within. It becomes part of the everyday tasks for everyone involved, is auditable and includes many checks and balances that significantly reduce the risk of non-compliance.



Another challenge facing companies today is how to proactively and efficiently manage product environmental compliance when the number of restricted and reportable substances continues to grow and evolve globally over time.

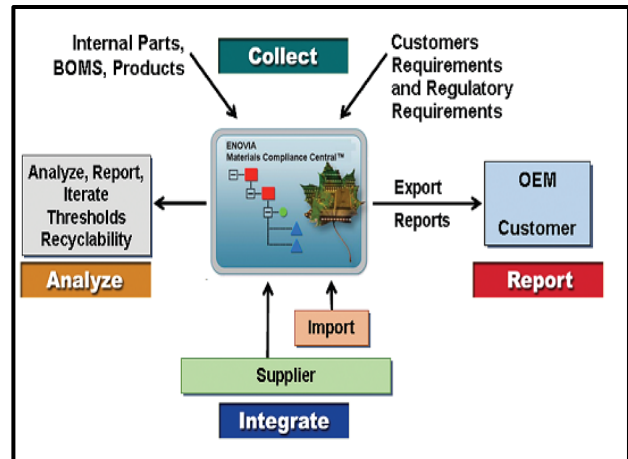
Achieving compliance can no longer be viewed as a one-time effort and must be built around a sustainable and flexible framework.

Knowing what reportable and/or restricted substances products contain down to the homogeneous material level in a cost effective manner is one of the key challenge companies have to face today.

In order to accomplish this, AB SCIEX implemented Materials Compliance Central, integrating it within our ENOVIA Engineering Central PDM system.

This enterprise level implementation provides AB SCIEX with an integrated approach for a “Design for Environment” solution that is now deployed across all AB SCIEX sites globally.

Engineers will now have the ability to view the environmental compliance state of individual components, subsystems and products during all phases of design and release to production.



## Efficiency Improvements, Product Development and Manufacturing:

Although the RoHS compliance deadlines for products such as ours is not until 2016, it became increasingly apparent that obsolescence was going to become an issue well before the 2016 date. Starting as early as 2009 more and more non-RoHS compliant electronic components that were designed into AB SCIEX products during the 1990's were becoming obsolete and/or discontinued.

Component Engineering and PCBA manufacturers contracted out to produce our PCBA's found it increasingly difficult to source specific components and often had to rely on brokers or third party distributors who charged a significantly higher price for these increasingly rare components.

Realizing that this approach over the long term was going to be quite disruptive and expensive, AB SCIEX made a strategic decision in 2011 to reconfigure and/or redesign many of our legacy PCBA's on currently shipped products and make them RoHS compliant.

In the long run this made better business sense and allowed for additional benefits as outlined below:

1. Improved efficiency of the overall PCBA design processes, by automating many aspects of component and BOM data management.
2. Outsourced many of the routine PCBA development tasks allowing electrical engineering teams to concentrate on more value added tasks.
3. Mitigated existing component obsolescence issues and ensured that new components are selected on the bases of meeting/exceeding the expected remaining product service life as well as meeting environmental compliance requirements.
4. Created opportunities to update many legacy PCBA's to the latest lead free and design standards.
5. Allowed for the incorporation of reliability improvements on existing PCBA designs where manufacturing and field service reported specific concerns.
6. Realized up to 20 % cost savings/avoidance on specific PCBA's currently in production.
7. Streamlined the “Design for Environment” process across all disciplines and sites through the updating and creation of applicable internal Work Instructions and Quality Procedure.

## Integrating Global Supply Chain:

One of the key challenges facing AB SCIEX was how to establish frameworks for gathering data from suppliers in an efficient and cost effective manner.

After careful consideration the approach decided upon was one that balanced the effort required to gather data directly from suppliers against obtaining it from third party providers. The primary advantage of this approach was savings in time and money. Third party environmental compliance data providers have established processes and efficiencies already in place and can provide the data in industry standard formats that can easily be uploaded into most environmental compliance management tools. They are also being viewed as viable alternatives by industry as well as the regulatory agencies today.

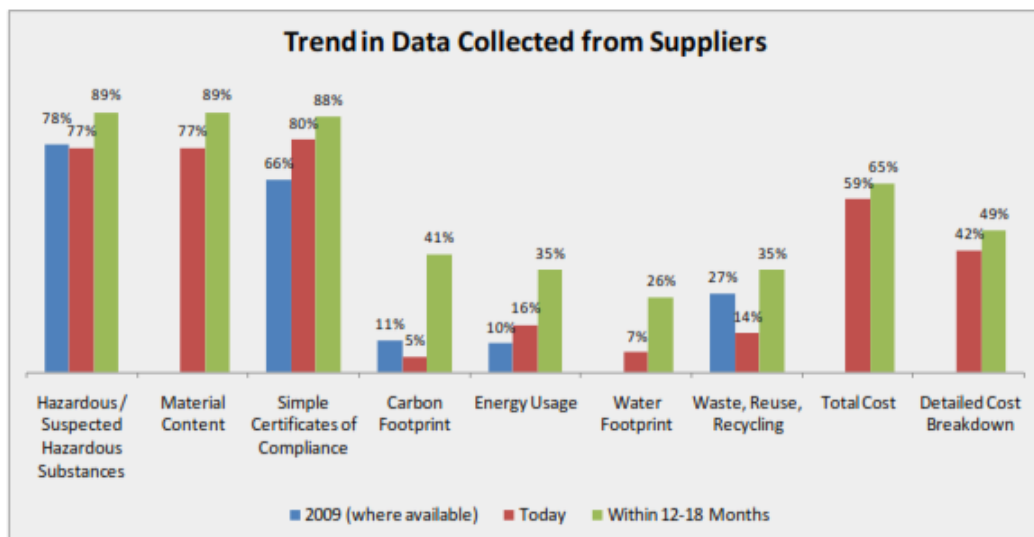
With this approach, suppliers of product related deliverables, built to AB SCIEX BOM specifications, are only required to report on the presence of restricted and reportable materials that they have added as part of their manufacturing processes.

For those subsystems where AB SCIEX only provided high level requirements, suppliers will be obligated to provide environmental compliance details around all reportable and restricted substances as outlined within the AB SCIEX Spec Environmental Requirement document.

AB SCIEX suppliers of deliverables are asked to provide material declarations, where applicable, utilizing the following prioritized methods of communicating the presence of restricted and reportable substances for each deliverable:

1. Full Material Disclosure
2. Materials Declarations
3. Compliance Statements
4. Test Data

Industry trends in data collection are clearly outlined in the following 2011 Tech Clarity table. It should also be noted that the most efficient long term approach to data collection is to gather full material disclosure information from suppliers and is being recognized today as the most efficient way of managing environmental compliance as the number of restricted substances grows each year.



To overcome these challenges AB SCIEX launched a formal supplier integration program within the past year to begin the process of education on current and upcoming environmental compliance requirements and how important it was that they work with us towards achieving the our program goals in the most cost effective and efficient manner.

Some of the key program elements in integrating Global Supply Chain include:

1. Product environmental compliance requirements and cost goals must be achieved in parallel.
2. AB SCIEX "Spec Environmental Requirements" will be available on the AB SCIEX external WEBSITE for easy access by suppliers.
3. Environmental compliance requirement are built into the purchase order Terms and Conditions.
4. AB SCIEX suppliers are required to provide details on reportable and restricted substances only on those deliverables that do not have detailed AB SCIEX BOM's where all components and equivalentents are specified.
5. Asking specific suppliers to join BOMcheck.
6. Rating suppliers on their ability to provide environmentally compliant deliverables based on criteria established by BOMcheck.
7. Making compliance to AB SCIEX's Spec Environmental Requirements mandatory, except where exemptions are granted.
8. Utilizing industry standard formats for environmental compliance data processing such as IPC 1752 and IEC 62474.
9. Addressing any intellectual property issues and concerns.

## **Leveraging External Expertise and Support:**

Navigating the ever evolving global environmental landscape can be a mind boggling task for those starting out as they attempt to understand this ever evolving and complex landscape. None the less, since 2006 the road has been well paved by others and the challenge before everyone today is how best navigate this landscape to get the information needed in order to achieve environmental compliance in an efficient and cost effective way.

At AB SCIEX, key collaborations with several consultants were established early on that allowed teams to understand how best to build a comprehensive environmental compliance program.

This approach also provided senior management with the confidence that company risks were being mitigated at various levels by tapping into this type of expertise.

Listed below is a partial list of collaborators and consultants utilized at AB SCIEX that provide unique capabilities to specific challenges encountered throughout all phases of implementation:.

- BOMcheck
- Claigan Consulting
- Compliance and Risks, C2P
- Dassault
- Dfr Solutions
- Environ
- ERA Technologies
- Greensoft
- L & T
- TATA (TCS)
- Tetra Tech
- Total Parts Plus



## **Updating Quality Management System Documentation:**

In order to drive environmental compliance from within the organization a parallel effort was taken to ensure all of the discipline specific Quality Procedures and Work Instructions were updated to reflect their specific responsibilities.

A matrix table was set up and each discipline was assigned responsibilities within one or more of the areas tabled below in order to obtain full coverage across all departments involved with various aspect of environmental compliance management:

1. Regulatory Compliance Landscape
2. Mitigating Risks
3. Substance Restriction Management
4. Intellectual Property Protection Provisions
5. Supplier Qualification and Certification
6. Configuration Management
7. Contamination Prevention
8. Recycling
9. Training
10. Product Environmental Compliance Documentation
11. Compliance Certification
12. Accountabilities
13. Environmental Compliance Records Management










## **Measuring Success:**

As with any program, having the ability to measure progress during the implementation phases was established from the start. Key program elements were then further subdivided into tasks that needed to be accomplished in order to have that particular element completed.

Quarterly reports were done to senior management through steering committee meetings for a two year period to ensure that the appropriate levels of funding, resources and capital expenditures forecasted were properly vetted and approved.

The following table provides an overview of the key elements that formed the bases of our program at AB SCIEX over the past three years in successfully implementing an enterprise level environmental compliance program.

## Key Elements of Success

Element	Description	Status
1	Quality Management System and all related documentation updates have been completed to reflect Product and Chemical Regulatory Compliance requirements.	
2	Internal and external design teams have access to the latest Product and Chemical regulatory compliance requirements.	
3	New products are being designed and released Product and Chemical compliant at launch.	
4	Understanding and communicating Product and Chemical Environmental Compliance Requirements and deadlines to all component, system and subsystem suppliers.	
5	Manufacturing has all of the necessary controls and audits in place to ensure all raw materials are environmentally compliant.	
6	Suppliers being categorized measured and audited according to their ability to ship Product Environmentally Compliant hardware.	
7	All Field related issues related to supporting Product and Chemical Environmentally Compliant and Non-compliant products of the same design have been resolved.	
8	Associates are being trained around Product and Chemical related regulatory requirements.	
9	All existing products designated for shipment past compliance deadline have been updated to be Environmentally compliant.	
10	In case of a country specific external and/or internal audit, proof of compliance can be clearly demonstrated.	

## Summary:

Today, AB SCIEX is well under way in establishing a viable and sustainable product environmental compliance program.

In looking back over the past several years, the key elements that allowed our program to progress and succeed are listed below:

1. Promote and instill a “Design for Environmental” mentality amongst all of the key stakeholders and department teams involved across the organization.
2. Integrate key elements of development, components engineering, supply chain and manufacturing through efficient, sustainable approaches.
3. Formalize data collection from suppliers that is repeatable, sustainable and allows for integration of multiple formats, from a variety of sources and standards.
4. Balance the risks and costs associated with the reality of standards adoption and evolution.
5. Keep all levels of management informed on compliance risks, costs, and sustainability information at the right level of detail in the context of product data.
6. Continuously review product roadmaps allowing for tradeoff analysis to be made around which products to continue, convert and/or retire based on potential returns on investment dollars.
7. Enable “Design for Environmental” approach through fully integrate, sustainable processes and systems, optimized for cost and efficiencies across the organization.
8. Maintain assurance of supply during all phases of implementation.

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