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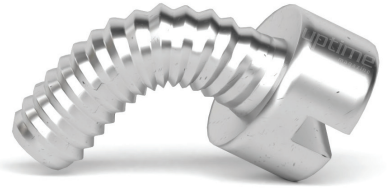


HOW MEDIMMUNE KICKED THEIR COGENERATION PROJECT INTO OVERDRIVE

Chad Kellner, Wayne Fieldhouse and Lee Harrelson

MedImmune is the biologics and biotechnology research and development (R&D) arm of the pharmaceutical and biopharmaceutical manufacturer AstraZeneca. MedImmune is the mind behind many popular pharmaceutical products on the market today, including Synagis®, a preventative treatment against severe respiratory infections in infants, FluMist®, an influenza vaccine administered as a nasal spray, Imfinzi®, an immunotherapy for cancer, and monoclonal antibodies Fasenra® and Siliq™.

MedImmune and AstraZeneca are no strangers to robust energy management. In 2014, their Gaithersburg, Maryland, campus qualified for a Silver Superior Energy Performance® (SEP), a certification for industrial facilities based off ISO50001's global energy management system standards. SEP certifications were developed by the U.S. Council for Energy-Efficient Manufacturing and are awarded by the U.S. Department of Energy (DOE) to industrial facilities that demonstrate a data-driven, transparent approach to energy management and excels in developing supporting systems.

According to the DOE, the Gaithersburg facility saved an annual $247,000 in "low- to no-cost operational improvements" as a result, after investing only $139,000, which the company reclaimed after seven months. The SEP certification project included, in part, the decommissioning of two unneeded boilers and the construction of a building certified by the Leadership in Energy and Environmental Design (LEED) program under the U.S. Green Building Council (USGBC).

WHAT IS A COMBINED HEAT AND POWER (CHP) SYSTEM?

CHP systems, also known as cogeneration plants, are energy generation assets that burn natural gas or other combustive fuel sources to produce both electrical and thermal energy.

Many hospitals, manufacturing plants, institutional campuses and other types of industrial and/or asset-intensive facilities use CHP systems.

MedImmune's efforts also earned it a Global Safety, Health and Environment (SHE) Excellence award and local certification as a green business through the Montgomery County Green Business Certification Program.[1]

But, MedImmune and AstraZeneca did not stop there. After extensive analysis of their facilities, they set out to accomplish an ambitious, three-pronged energy management project: the design, engineering and installation of combined heat and power (CHP) systems. This one CHP installation would help the companies make considerable progress across all three of the following areas of improvement:

1. Decrease facility operational costs

Pharmaceutical production is far less energy intensive than other types of manufacturing. Cement processing and steelmaking, for example, with their enormous crucibles burning around-the-clock, certainly require much more thermal energy and, thus, operate with much higher energy costs than the measured demands of pharmaceutical laboratories equipped with reactors, digesters and sterilizers.

Regardless, the American pharmaceutical industry still spends, in total, approximately $1 billion on energy every year, according to the latest DOE research.[2] These costs represent an opportunity for organizations within the industry, particularly research and development facilities like MedImmune, to optimize energy expenditures through intelligent technological investment and divert operational cost savings to the funding of scientific exploration.

2. Reduce corporate carbon footprint

Like others in its field, AstraZeneca has sought to reduce carbon emissions across the breadth of its operations. In an environmental sustainability report it published in 2015, the company said it had cut its carbon by 21 percent between 2010 and 2015.[3] On its website, AstraZeneca said it has decreased its carbon footprint by another five percent in the past two years.[4]

Industrywide, there is still much to be done. Leaders at AstraZeneca and MedImmune believe that on-site cogeneration will empower them to reach their current environmental sustainability goals regarding carbon emissions and do so faster than other alternative fuel sources, thus giving them new opportunities to set even more ambitious efficiency objectives for the future.

3. Increase power reliability and resiliency against outages

It is no secret that energy transmission and distribution infrastructure across the country, mostly erected in the mid-20th century, has long surpassed its lifecycle. The rising occurrences of extreme weather phenomena also pose a significant threat to asset reliability in the industrial sector.

The utility grid in Maryland is no exception. According to one estimate from 2016, the state experienced 57 outages over the course of the previous year, affecting more than 145,000 residents. Nearly half of the reported blackouts were caused by either equipment failure or human error.[5] On-site cogeneration would effectively strengthen MedImmune against these threats by allowing its facilities to generate their own energy as needed in the event of a blackout.

HOW A CHP SYSTEM WILL HELP MEDIMMUNE REACH THESE OBJECTIVES

A well-designed CHP installation can deliver several benefits in an effort to control energy usage.

First, CHP systems boast a higher efficiency than a typical utility grid connection. On average, energy transmission along a utility grid results in losses that occur as energy travels from the generation plant to the electrical load, sometimes many miles away. This method is only about 30 percent efficient.

On the other hand, CHP systems operate at 65 percent efficiency or greater. Apart from efficiency gains from the close proximity of the CHP system to the electrical load it serves, it also reclaims heat created in the energy generation process and can put it to use in the adjacent buildings. The addition of an absorption chiller on the CHP system would provide usable cooling from that waste heat, thus securing year-round thermal, as well as electrical loads.

CHP systems also allow users to capitalize on an economically advantageous spark spread. Spark spread is a metric that estimates the theoretical gross margin between the price of a unit of generated electricity and the cost of the fuel required to produce the same unit of electricity. In this case, low natural gas prices and high electrical rates make a CHP installation a viable, long-term financial investment for MedImmune.

Finally, an on-site CHP system gives users the option to operate independent from the energy grid. When the system is placed in island mode, users can generate electricity and heat without a direct connection to a utility. Resiliency against power outages is valuable to any facility reliant on uninterrupted uptime, let alone an organization like MedImmune that conducts important and costly pharmaceutical research.

> “…The American pharmaceutical industry still spends, in total, approximately $1 billion on energy every year…”

THE SCOPE OF THE PROJECT

After consulting with specialists from GenesisSolutions, a business management group, and Buch Construction, MedImmune decided to install a 2.5 megawatt natural gas-fired reciprocating internal combustion CHP system.

The system would initially connect to a medium voltage switchgear serving a portion of One Medimmune Way called Area 6 in the Gaithersburg campus. Energy analysis showed that Area 6 had the largest electrical load and available switchgear capacity to tie in a new CHP unit. However, before connecting the CHP system to the existing campus-wide energy infrastructure, eight different utility electrical services feeding into adjacent campus buildings would require consolidation with the two Area 6 services onto a single campus-wide medium voltage switchgear with two new redundant utility feeders. A parallel switchgear would be added to tie together two existing 3 megawatt diesel generators to the proposed CHP unit. This would allow the MedImmune campus to respond quickly to an immediate outage, as well as sustain long-term generation during a prolonged outage event.

Installation also would require connecting the CHP system to distinct existing heating plants on the MedImmune campus. Stakeholders targeted two optimal areas where connections would provide an operational benefit to the project and retain cost efficiency.

Area 6 contains three, 26,000 pound-per-hour steam fire-tube boilers. The design team also discovered a recently installed steam cross-connect, which effectively tied multiple steam distribution systems together. With this recent system upgrade, the new CHP system could connect to the Area 6 boiler plant since it was located closer to the proposed cogeneration site and could still serve the steam loads throughout the entire campus. Exhaust gas from the proposed CHP system would feed a new heat recovery steam generator (HRSG) boiler to produce steam at about 100 pounds per square inch to preheating coils in the air handling units, process equipment and hot water heat exchangers via this existing piping network.

Since the CHP also produces about 5,500,000 BTUs per hour of 200 degree hot water, the design included a new hot water riser up through the building to connect to the existing 1,600 gallon-per-minute Area 6 hot water reheat system. Finding space for the piping and coordination installation of this riser in an operating lab environment was a major design and construction challenge that benefited from effective project management by involving contractor, engineer and owner to evaluate solutions.

Although analysis showed that most of the heat produced by the CHP could be used to heat the building, the design included provisions for a future 500 ton double-effect absorption chiller that uses steam and hot water to produce chilled water to maximize year-round CHP efficiency. This component was planned to supplement the existing Area 6 cooling plant with its two, 1,600 ton water-cooled electric centrifugal chillers and an 800 ton water-cooled electric centrifugal chiller.

Because of the proximity to both electrical and thermal loads, project stakeholders ultimately agreed that the Area 6 location would be the best location to construct the new CHP system.

PROJECTED RESULTS

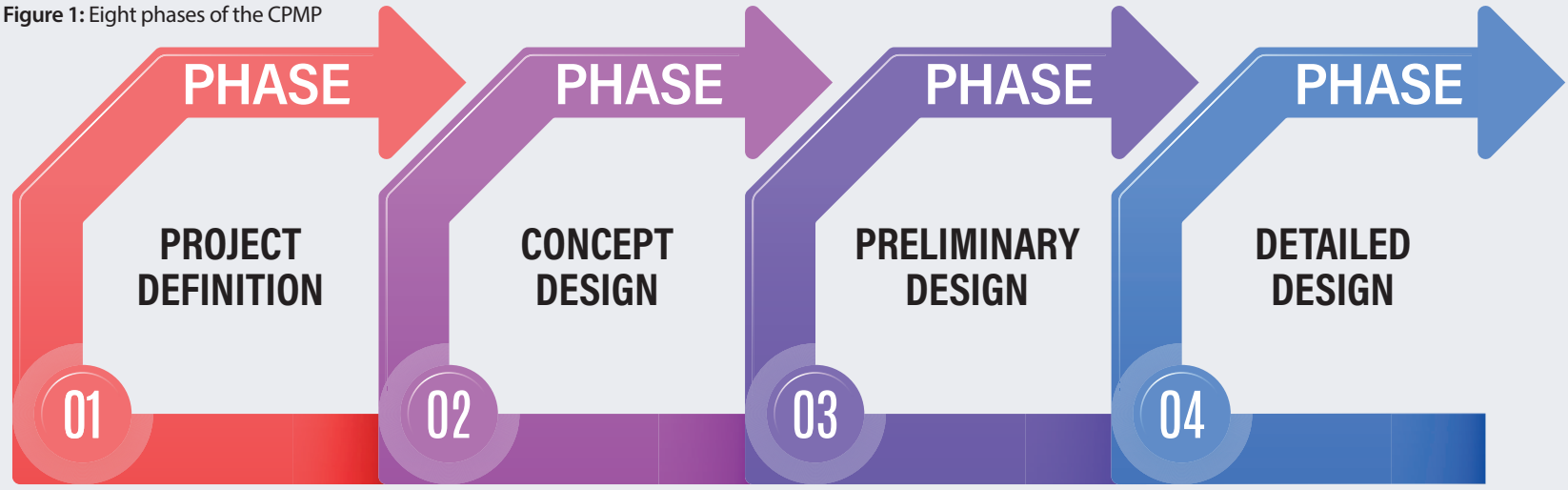
So, in the end, what would the sum of this effort deliver to MedImmune and AstraZeneca in hard numbers?

To uncover the answers, specialists reviewed the proposed design drawings, conceptual system designs and simulated energy outputs, then constructed a financial model for determining the energy cost savings potential. This model incorporated the cost of energy consumption, maintenance, construction and capital parameters.

Part of the analysis included the creation of a custom-built building energy model developed with help from MedImmune's building automation system, which tracked historical electricity consumption and thermal performance. Specialists also analyzed alternatives to the proposed CHP, such as gas turbines, microturbines and fuel cells, as well as alternately sized cogeneration assets. Specialists ultimately concluded that the proposed 2.5 megawatt CHP engine was the best choice once all campus loads were consolidated.

If the project went according to plan and the equipment proposed operated to specification, MedImmune would decrease its annual electrical consumption by about 14.4 million kilowatt hours per year and save more than $900,000 in energy costs and $550,000 in operational costs annually.

Figure 1: Eight phases of the CPMP



- Request for Engineering Department Assistance Form

- Project Scope Document
- User Requirements
- Concept Design Report
- Environmental, Health and Safety (EHS) Checklist
- Project Summary Schedule
- Conceptual Cost Estimate

- Team Charter
- System Impact Assessment
- Approved System URS (User Requirement Specification)
- Approved Basis of Design Document
- Document Approval Matrix
- EHS Project Plan
- Project Summary Schedule
- Control Budget
- Monthly Status Report
- Quarterly Capital Expenditure (CapEx) Forecast

- Project Execution Plan
- Component Impact Assessment(s)
- Documented Enhanced Design Review
- Hazard and Operability (HAZOP) Assessment (or similar)
- Issued for Construction (IFC) Documents
- Approved System Functional Requirement Specification (FRS)
- Construction Safety Plan
- Approved Commissioning Plan
- Approved Validation Plan or Change Control
- Integrated Project Schedule
- Trending Cost Estimate
- Monthly Status Report
- Quarterly CapEx Forecast

After factoring in construction and maintenance costs, the investment in the CHP system project would pay for itself in as little as eight years.

But, let's be honest. How many engineers, project managers and their respective teams have said, "if all goes according to plan" before eating those words later when their complex projects run well over time, over budget and light-years out of scope? Going into this project, it was possible this could easily become such an undertaking.

So, how did MedImmune prevent the project from succumbing to all the traps other large-scale capital projects have fallen into in the past?

INTRODUCING THE CAPITAL PROCESS MANAGEMENT PROCESS

The Capital Process Management Process (CPMP) goes into great detail by defining the lifecycle management requirements for new or modified facilities compliant with the current Good Manufacturing Practices (cGMP) by way of eight phases and their related documents. See Figure 1.

CPMP not only covers cGMP-compliant facilities, but also related equipment and utility systems used in the manufacture of clinical trial materials, active ingredients, drug substances, commercial pharmaceutical products and vaccines at those facilities.

As the name suggests, CPMP was built with a specialized focus on developing comprehensive and compliant frameworks for large-scale projects that incorporate advanced computer systems and multiple functional teams.

Note: Project teams can also adopt a simplified alternative CPMP for smaller, less complex projects with low capital costs.

THE PRIMARY DISCIPLINES OF CPMP

To help in understanding at a glance the value of CPMP to complex capital projects, the entire methodology has been distilled into three key components:

1. Collaboration among team members

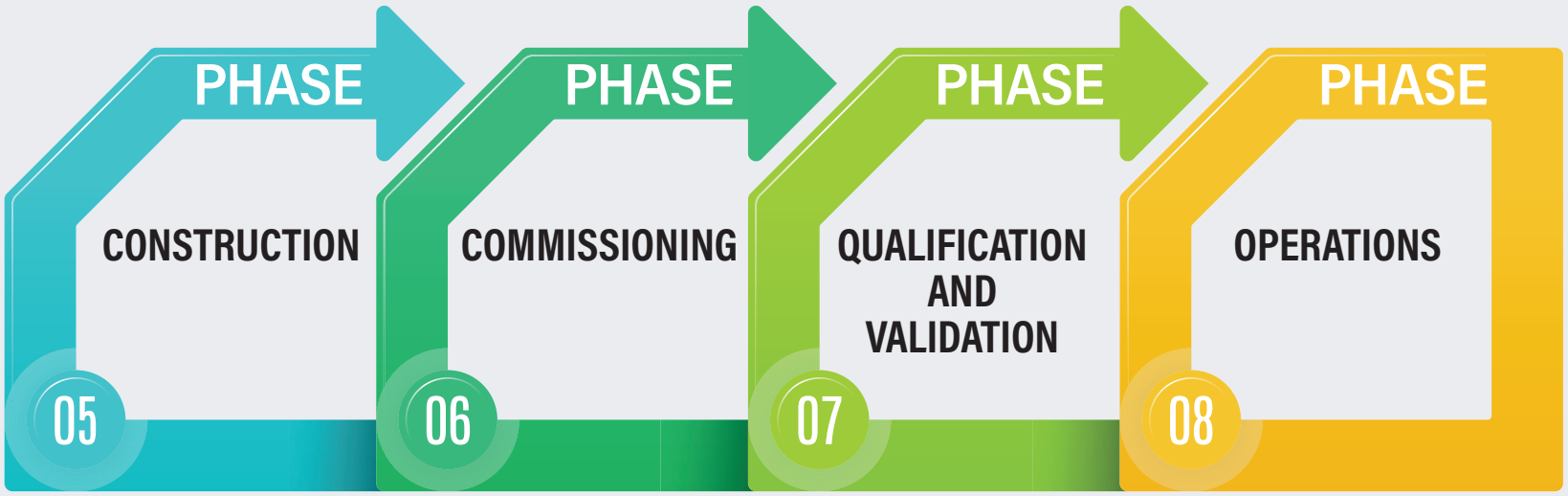
Under CPMP, there is no such thing as over communication. CPMP cannot exist in a project environment that lacks cooperation and coordination between team members.

That is why CPMP mandates at the outset the creation of a project team, as well as the designation of the respective duties members uphold:

- **Project Sponsors** – Initiate projects by justifying them to decision-makers, crafting budgets and obtaining approval from aforesaid authorizing bodies. Throughout the project, they act as overseers.
- **Project Leaders** – Represent Project Sponsors as the team member responsible for project execution from the justification stage through initial production. They lead Project Engineers/Managers.
- **Project Engineers/Managers** – Supervise day-to-day actions regarding design, construction and commissioning. They may also support validation and qualification processes as needed.

The following are brief descriptions of project functions under which team members serve:

- **Project management function** pertains to project administration, planning and execution.



- Operational Readiness Review(s)
- Punch List Report
- As-built Documents Issued
- Approved Commissioning Test Plan(s)
- Integrated Project Schedule
- Cost at Completion Forecast
- Monthly Status Report
- Quarterly CapEx Forecast

- Approved Care, Custody and Control Transfer
- Record Documents
- Turnover Package
- Approved Commissioning Summary Report
- Integrated Project Schedule
- Cost at Completion Forecast
- Monthly Status Report
- Quarterly CapEx Forecast

- Approved Qualification Protocols
- Approved Validation Summary Report
- Integrated Project Schedule
- Cost at Completion Forecast
- Monthly Status Report
- Quarterly CapEx Forecast

- Project Closeout Report
- Postmortem

- **User Group/Operations function** is concerned with compiling input on design specifications, assessing impact and performing operational training.
- **Engineering function** includes system design to the exact specifications set forth by Operations team members, safety reviews of said designs and document preparation for commissioning, qualification and validation functions.
- **Construction function** is responsible for asset construction and installation, along with equipment preparation and corroboration between asbuilt drawings and finished product.
- **Commissioning function** ensures installed equipment/utility systems are compliant, meet quality standards and are functioning as designed.
- **Technology/Validation function** inspects systems and system performance against established specifications.
- **Environmental, Health and Safety function** performs initial safety checks on facility, equipment and utilities, as well as performs a review of the project design before project commencement.

At the very minimum, each of these functions must have representation within the team from the start of the project for the CPMP to work. Depending on the nature of the project and agreement among project team members, additional functions may include **Information Systems, Maintenance**, **Regulatory Affairs** and **Purchasing**.

2. Compliance and safety

A moment of discovered noncompliance with government or regulatory authorities can stymie a project nearing completion or unravel a completed project. What's more, injuries sustained during project implementation can do the same, as well as deprive the team of a valuable member or members.

Capital projects, in particular, are at risk because of their many layers and moving parts, which is why CPMP insists on the highest standards for equipment use. All assets, built or tools utilized in the building process, must be the right design, size and capacity.

CPMP also promotes best practices in design, implementation and construction of cGMP capital projects involving assets that may come into contact with drugs and other chemicals. Equipment surfaces must not react to, add to, absorb, or in any discernible way affect in-process materials or components.

3. Precise documentation

Every capital project has its fair share of paperwork. Documentation, when utilized well, can act as a series of gateways. A system of mandatory forms in place can stop team members from racing ahead without necessary information, or force them to reflect on whether the proper checks and balances have been administered.

CPMP uses several unique documents and related resources that are spread among all project stakeholders to ensure accountability. They are:

Project Scope Document (PSD): General accounting of the project as a whole. Includes the official description of the project, designations for all team members and a detailed itinerary of its implementation. Management will review and approve the project as it is presented in the PSD.

Document Approval Matrix (DAM): Essentially, an index for document assignment. DAMs outline which team members are responsible for generating, reviewing, approving and storing each specific CPMP document.

Impact Assessment (IA): Every established system within a given project requires a delineated boundary, as well as analysis confirming those boundaries have not been crossed. IAs look for direct, indirect, or no impact on the product.

User Requirement Specification (URS): An appraisal of the expected performance of constructed or purchased equipment or systems. URS may include data regarding capacity, materials of construction, operational characteristics, cleaning requirements and more.

Conceptual Design: Design stage to generate various alternatives for evaluation. The project team then selects the concepts to be taken forward into the Basis of Design stage.

Basis of Design: Approved document(s) that define(s) the user requirements, critical functions, or critical parameters for facilities, equipment and support systems, and descriptions of system boundaries.

Enhanced Design Review: Documented review and verification of the proposed design. Determines whether the design is suitable for its intended purpose and conforms to operational and regulatory expectations.

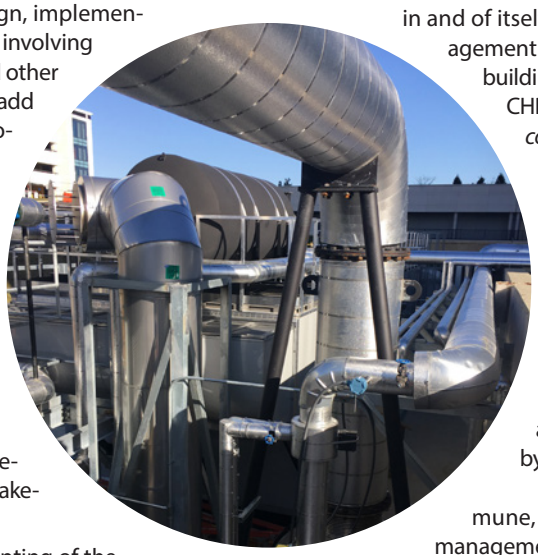
Functional Requirement Specification (FRS): A document that delineates the operational characteristics of the equipment/system, as well as any design or construction details that have cGMP implications. It is utilized as the basis for any design, Factory Acceptance Tests (FATs), Site Acceptance Tests (SATs), commissioning and validation activities.

Engineering change management (ECM): The process of determining the impact of proposed or actual changes on cGMP facilities, equipment and utilities. Changes made after the approval of the final design review through the Operational Qualification (OQ) report approval are subject to ECM.

THE RESULTS OF THE CHP PROJECT

By the end of MedImmune's CPMP, it had achieved all the goals it had set out to accomplish. Cogeneration allowed the organization to use natural, gas-fired electricity more efficiently, reduce energy-related expenses by leveraging spark spread and prevent uptime losses by creating an emergency on-site energy generator, all while still connecting to its regional utility.

Apart from operational and efficiency gains acquired by MedImmune and AstraZeneca, the implementation of the CPMP methodology was, in and of itself, a testament to the very best the project management discipline has to offer. The project team finished building, installing and reviewing all components of the CHP project *five months ahead of the original projected completion date*. MedImmune is currently progressing toward a formal modified version of the system to utilize for all capital projects.



Currently, MedImmune is considering a second, unrelated CHP project, an exciting prospect made possible thanks to the initial electrical consolidation effort initiated after the first CHP project. Such an opportunity would further MedImmune's vision of a research and development facility powered by environmental sustainability impervious to outages and unencumbered by high energy costs.

Since the completion of the first CHP, MedImmune, with assistance from its engineering and asset management specialists, has laid out a scope for additional CHP technology, including intelligent automated sequencing controls that would switch the system in and out of island mode as necessary and activate the system automatically without manual intervention.

A COLLABORATIVE EFFORT

This project would not have been possible without a collaborative effort among many individuals.

Chad Kellner, MBA, CMRP, the director of site operations, engineering and budgeting for MedImmune is recognized for his insight and supervisory role throughout the scope of the project. In fact, each member of the Med-

Immune team who participated in the CPMP process deserves recognition for their astute user input into the design of the CHP plant and cooperation throughout this immensely complicated endeavor.

No capital project is accomplished by a single person, contractor, or organization. The success of this project is due to a few incredible leaders. Special gratitude to the following individuals for their support and assistance:

- Mark Battaglia, Senior Manager, Facilities Projects at MedImmune Engineering;
- Andy Hernandez, Principal Electrical Engineer, AstraZeneca Engineering;
- Jeff Williford, Project Manager and John Pearson, Superintendent, at Buch Construction;
- Phil Miller, Foreman at Heffron Company;
- Chuck Barber, Project Manager and Shawn Neylon, Foreman, from JE Richard Electrics, Inc.
- Bob Hayes, Commissioning Engineer, formerly of the commissioning firm MBP.

These professionals came to the worksite every day with a smile, a kind word and plausible suggestions for any and every issue that was encountered.

REFERENCES

1. https://energy.gov/eere/amo/articles/earning-sep-silver-certification-leads-medimmune-significant-savings
2. https://www.energystar.gov/ia/business/industry/LBNL-57260.pdf
3. https://www.astrazeneca.com/content/dam/az/our-company/Sustainability/Environmental-Sustainability.pdf
4. https://www.astrazeneca.com/sustainability/environmental-protection.html
5. http://www.sustainablepowersystems.com/wp-content/uploads/2016/03/US_BlackoutTracker_2015_Final.pdf

Chad Kellner *is the Director of Site Operations Engineering & Budgeting for MedImmune. Chad leads a team of multi-disciplinary engineers and designers to deliver state of the art, energy-efficient office, lab and manufacturing facilities for biologics research and development.*

Wayne Fieldhouse, *PE (NJ), is a Principal Reliability Engineer and Project Leader for GenesisSolutions, An ABS Group Company.* ***Lee Harrelson,*** *PE, LEED ® AP, a Principal Engineer at CMTA Consulting Engineers. Wayne developed the standard operating procedure for the Capital Project Management Process, along with his former colleague, George Wolf, PE. Lee and his team were the masterminds behind the system, components and controls.*
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