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DR. BETTY THERIAULT: A GREAT SUCCESS AT AALAS 2021!

President of the International Association for Gnotobiology, Dr. Theriault has received an Award from the AALAS Board of Directors



Dr. Theriault has been nominated by the Committee on Laboratory Animal Training and Research (CLATR) for the Pravin N. Bhatt Scientific Investigator Award and to have the nomination endorsed by the AALAS Board of Directors.

The award was first created by AALAS in 1994 and in its current format is intended to recognize individuals who have made significant scientific contributions to laboratory animal or comparative medicine and have also contributed to the AALAS community through dissemination of their work in various formats such as local, regional and national meeting presentations, posters and publications, as well as mentoring of trainees or others in the laboratory animal or comparative medicine community. The recipient of the Bhatt award is also invited to present the Wallace P. Rowe lecture at the AALAS national meeting.

Dear Dr Theriault, firstly congrats! Can you tell us more about the award and your talk?

Thank you! It has been such an honor to have been nominated for the Pravin N. Bhatt Scientific Investigator Award. This invitation was quite humbling. Both Drs. Bhatt and Wallace were giants in virology, comparative medicine, and their contributions to the laboratory animal profession. While much of my participation at national AALAS meetings has been on gnotobiotic technology and facility operations, my scholarly activities have been in animal model design and development.

It was a great opportunity to share with the community several animal models we have been developing in recent years at The University of Chicago, scientific advances they support and the surgical preparations requiring fastidious attention to sterility and detail that these models demand for success.

You are managing a very complex facility! What have been the toughest difficulties in managing your facility during Covid lockdown?

Our facility has been very fortunate. As our researchers ramped down their work (rapidly), and we pivoted to

asynchronous staffing teams, we were very well positioned to support our unit's operations.

I think the strength of our team, their professionalism and their resolve enabled us to remain nimble on an ongoing basis.

From the inception of the pandemic, we were classified as essential personnel due to the need to care for the animals we oversee.

Of course, as we were outlining color codes for the phases of operation we would enter, mainly driven by available staffing to support unit operations and animal care, there was so much uncertainty. The high incidence of COVID-19 infection and deaths for Chicago in the Spring of 2020, coupled with the civil unrest we were experiencing in the United States and very tangibly in Chicago made every day seem like a high alert day. It was very intense. The animal care staff was just amazing! They were truly heroes for their dedication and determination to care for the animals and protect our scientist's research. The resolve to show up each day with so many personal and societal challenges cannot be overstated and go unrecognized.

What did you learn from this period and what do you suggest to your colleagues to consider for Guidelines for a Gnotobiotic facility?

So much was learned. As an AAALAC international accredited program, we already had an emergency response plan in place. A rapidly emerging global pandemic was not one of the emergencies specifically described! We were in good shape however as relates to the needs of the animals, specifically food, water, bedding, health observations.

Our gnotobiotic facility is a "centrally" managed facility and program within our broader animal care program. This positioned us well with myself as a veterinarian and all of the staff classified as essential personnel. This afforded us the ability to retain access to manage critical functions which included the specialized care for the germ free and gnotobiotic animals.

Managing communications, creating a stable and supportive at work and remote work environment for the staff and affording flexibility to meet facility and staff needs during a time of crisis was critical. We used many



electronic support services available to us to achieve this. Having candid and realistic conversations with the researchers that we support also facilitated planned completion of ongoing experimental work, prioritizing plans for studies once new projects could be launched and maintaining colonies to be most favorably positioned when restrictions loosened was also of great value. I am also a strong advocate of cross-training and redundancy. These strategies also helped us greatly so we could operate successfully with the reduction in labor density.

What is your feeling about Gnotobiotic trends in the next years after Covid period?

I believe it will be robust. We have seen that correlations abound with respect to the influence of the microbiome on human (and other species) health and deviations from health and/or disease. **Although much active research was paused for several months, research activity was not.** Virtual meetings continued with exchange of information and new data. Manuscripts were completed and published. Time to reflect and plan was used strategically and judiciously by the research community. **We have seen a robust return to research activity and ongoing promise in the microbiome field as well as demand for gnotobiotic services.**

Do you think we will see an acceleration of Science in gnotobiology?

Absolutely. There remains so much to be discovered. So much more understanding of biological systems can be elucidated, and so much potential for novel therapeutic interventions in the biomedical field.

The acceleration of science in gnotobiology was driven by new "omic" technologies 15-20 years ago. These technologies have become more accessible, less costly, and expertise in data analysis in the omic fields has markedly developed.

I anticipate demand for gnotobiotic technology and animal models will remain high. The future looks bright!

LEOPOLDO ZAUNER
MARKETING & COMMUNICATION DIRECTOR
TECNIPLAST S.P.A.

TECNIPLAST PRODUCTION SYSTEM: AN IMPORTANT MILESTONE FOR THE COMPANY

Alessandro Del Ponte, TPS & IPS leader introduces the innovative program



Tecniplast has been introducing continuous improvement in the organization for three years now. Can you tell us what TPS & IPS are?

Tecniplast Production System (TPS) & IWT Production System (IPS) are based on the culture of the World Class Manufacturing System

(WCM). **The WCM is an innovative and continuous improvement program strongly oriented to the customer and corporate people, with the aim of attacking all kinds of waste and losses, thanks to the rigorous application of methods and standards through the involvement of every worker/work role.**

Composed of ten technical pillars and ten managerial pillars, the WCM defines, through a detailed assessment, a path of improvement. This takes place in seven steps by initially acting on the model areas and expanding horizontally on all other areas after reaching the standard level. **The WCM is based on the creation of value in relation to its costs.**

Developed in America in the 1980s by Richard J. Schonberger and later by Professor Hajime Yamashina, it stems from a set of Lean manufacturing methodologies developed in Japan since the early 1900s. It arrived in 2005 in FCA's Italian plants, spreading around the world as a structured and effective operating model.

What are the objectives that the program has in a complex organization such as TP/IWT?

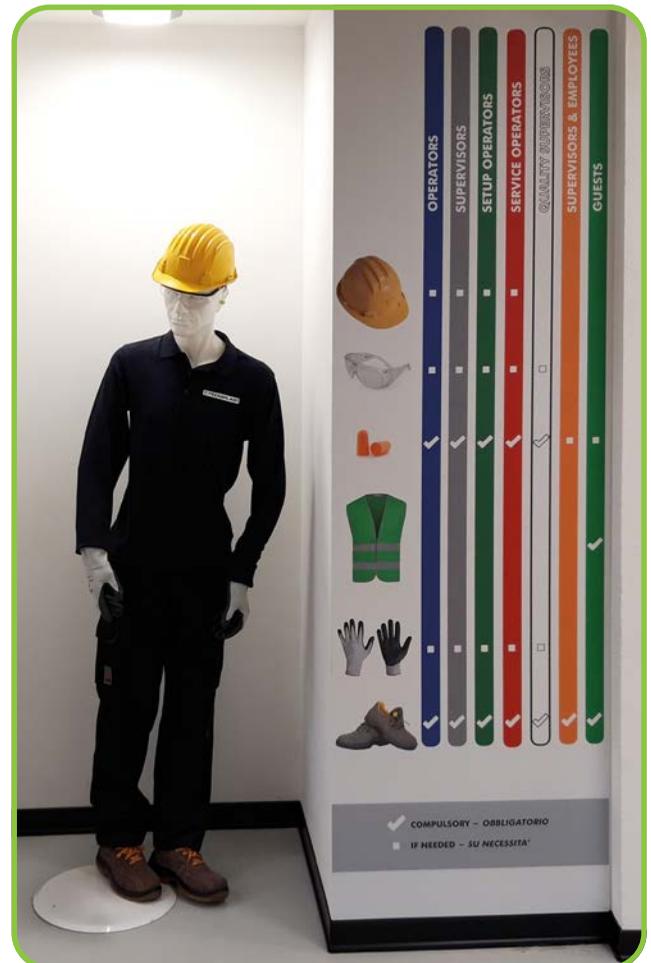
Starting from our vision and needs to build the TPS, following the WCM culture we are working hard to create our factory management model. We want to create a new type of organization that works as a group in problem analysis and solution search. This is the first major goal achieved together with safety culture, involvement of people and customer care.

The concept of **"zero optimum"** (zero stock-zero injuries-zero scraps) is no longer an abstract goal but a concrete result that we want to achieve on time on budget.

Could this be a strategic direction that only a few companies have chosen? Therefore, are TP/IWT innovators?

Certainly, TP and IWT are innovators and able to look beyond the immediate.

In 2017 the ownership decided to measure the opportunities for improvement of its production system with **the Best In Class levels related to the organization**. To do this, a BellaFactory audit (Ergo Foundation, a leader in the field of management consulting) was carried out and the process of change went into operation as a result of this assessment. Very few companies spontaneously choose to join and invest in such a structured and challenging program, with an innovative vision from top management, who believe in the new TPS. **A solid commitment from the company's**





top management fosters organisation alignment towards our shared ultimate goal of 'Operational Excellence' while overcoming barriers.

It has been three years since its introduction. Can you already see results in the application of program rules?

The factory is different than it was three years ago, we breathe new air: that of profound change, not dictated by some ephemeral fad, but by something true that you are able to see, which is a beautiful factory that people can live in concrete terms.

We are not only talking about KPIs or daily team meetings on issues and structured activities of problem solving in search of root causes, but we talk about transformed, clean and organized areas, where the operators themselves have helped to change them, making them beautiful and efficient with the ideas and daily commitment of all.

This is the most important result: the ability to create stable, excellent, and standardized processes managed by trained, involved and inspired people working together in the same direction.

I also make no secret of the impact of economic results on improving efficiency indicators and the savings projects we are having: all this is truly remarkable and spurs us more

forcefully towards excellence, namely **"DANTOTSU" (being the best, far ahead of others).**

What do you think are the biggest benefits that a customer of TP/IWT products can have from the TPS & IPS?

For our organization, **the Customer is the supreme good.** Our commitment is to improve their satisfaction through what we do in everyday life, to take care of them both in the reactive and preventive phase (analysis on the critical issues present through problem solving methodologies eliminating the return of problems) and in the predictive phase (analysis to eliminate any possible future criticality).

One of the key principles of the transformation in TPS is "The Voice of the Customer in the Factory", which represents the knowledge of the needs of our customers directly in the factory. It may seem trivial, but it is thanks to the increase in sensitivity to customers by everyone that allows us to make a difference. Our customer today also becomes the downstream department, and this strengthens the principle even more.

ANDREA COMAI
DIRECTOR OF OPERATIONS
TECNIPLAST S.P.A.

The simplest compound for achieving a reliable and effective low-temperature bio-decontamination.

In this third and last episode of the hydrogen peroxide's saga, it will be argued how to face bio-decontamination cycle validation activities. When a system equipped with an automatic airborne disinfection system is sold, the supplier must also perform the bio-decontamination cycle validation, which can be divided into two phases:

Cycle Development, the procedure that allows to find a suitable recipe as a base for performance qualification purpose.

Performance Qualification, the cycle implemented according to the cycle development outcomes is run three times using biological and chemical indicators for demonstrating:

- Cycle efficacy against representative strain of micro-organisms (e.g. spore of *Geobacillus Stearothermophilus*);
- Cycle efficacy against a certain population of micro-organism (e.g. δ -log reduction).
- Decontaminant distribution on all surfaces exposed (load and environment).
- Cycle repeatability.

Recipe

Vapour phase hydrogen peroxide cycle development outcome is a set of parameters defining at least the duration, the injection rate and flow rate of the bio-decontamination cycle phases:

- **Warm-up or Dehumidification:** to prepare the environment for the H_2O_2 vapour injection.
- **Rising:** to get as soon as possible at the target concentration level (expressed in ppm).
- **Plateau:** to maintain the hydrogen peroxide concentration level constant.
- **Aeration:** to remove all the hydrogen peroxide vapour.

The set of parameters which define each phase is called recipe. For instance, the Rising phase and the Plateau phase must be defined at least by the H_2O_2 injection rate, the air flowrate, and the phase total duration. The warm-up and aeration must be defined at least by the air flowrate, and the duration of the phase. If the system is equipped with relative humidity and hydrogen peroxide concentration



Figure 1 Example of mapping of an empty pass-through chamber

sensors, the warm-up and aeration phases can last until RH% and H_2O_2 ppm reach the desired level. If we consider a bio-decontamination based on aerosolized hydrogen peroxide technology, the recipe is slightly different:

- Amount of H_2O_2 to be nebulized.
- Contact Time: time necessary to achieve the killing desired.
- Aeration time.

Challenge Points

The first activity carried out and documented during the Cycle Development is the definition of the load, which is made up of tools, disposable, miscellaneous, and whatever has to be bio-decontaminated by hydrogen peroxide. The environment (room, labs, isolator, pass-through, pass-box) and its load must be analysed to identify the "challenge points", that is those points in which cycle effectiveness may not be optimal (corners, filters, hard-to-reach area, etc...). The environment and its load are then mapped according to the worst scenario approach, which means that if the bio-decontamination method is effective against the challenge points, it must be effective for all other locations. There is no indication about the minimum number of points to be identified, nevertheless the mapping must have a good balance between an excessive number of points, which could lead to a waste of time and increase the risk of errors, and a poor mapping, which could give a not representative result. In any case the mapping of the environment and its load must be decided and documented together with the final user. Each point must be identified and labelled before proceeding with the indicators' placement.

Indicators

Once all positions are established, it is necessary to test the recipe to verify the correct decontaminant distribution through the environment and its load and, more important, to test the decontaminant efficacy. Decontaminant uniformity is tested using **chemical indicators** (CI).

Chemical Indicator is a substance that gives a visible sign, usually by a color change, of the presence or absence of a certain concentration of Hydrogen Peroxide (mg/ml), normally placed on a mechanical support, like paper strip or adhesive.



Figure 2 Adhesive chemical indicator pre and after exposure to hydrogen peroxide

Bio-decontamination cycle efficacy is tested using **biological indicators** (BI).

Biological Indicator is a test system that contains viable microorganisms with a defined resistance (D-Value) to sterilization process.

Mostly of BIs are stainless steel coupons or paper strips inoculated with a certificated population (typically 10⁶, 10⁵ or 10⁴) of viable spores of *Geobacillus Stearotherophilus*. To ease handling, BIs are often wrapped in Tyvek and nowadays they can be considered an industrial standard.



Why *Geobacillus Stearotherophilus*?

- Spores grown between 55÷60 °C are not dangerous for humans and prevent false positive due to facility microbial background.
- Very popular on the market, where it can be found at different population scale: 10⁶, 10⁵ or 10⁴.
- Dramatic Colour change of culture media for unbiased and easy verification.
- The long growth time (7 days) represents the limit of this technology.

Cycle validation pitfalls

The concept of Micro Condensed Hydrogen Peroxide (MCHP), introduced in the first episode, helps to explain the chemical and physical mechanisms behind the extraordinary decontamination power of airborne hydrogen peroxide, both in vapour and aerosol state.

MCPH is an invisible layer of micro-droplets with high concentration of hydrogen peroxide (MCHP) and its formation is facilitated under certain conditions. For this reason, VPHP is not only a time-concentration based process, but it is strongly influenced by the environmental condition, such as humidity, temperature, pressure and contact materials. Understanding how the several variables influence the cycle outcome is essential for a cycle validator. The higher the following parameters, the higher the cycle efficacy, because the formation of MCHP is facilitated.

- **Relative Saturation.**
- **Exposure Time.**
- **Relative Humidity.**
- **H₂O₂ concentration.**

On the other hand, a temperature increase reduces the cycle efficacy.

Although a high level of relative saturation is beneficial, frank condensation should be avoided. The trick is to stay close, but below, the dew point.

Typical pitfalls during cycle development are:

- Understand how temperature affects relative saturation.
- Relative humidity is not enough for condensation control.
- Select the correct material, considering that some plastics (like PEEK or ABS) have a high absorption and decomposition effect against H₂O₂.
- Presence of possible rogues in commercially supplied batches of BI.

Despite being now more than 30 years since the first gas phase sanitization process has been applied to an isolator, Vapour Phase Hydrogen Peroxide (VPHP) process continues to seem rather complex, and the cycle development appears almost mystical. This is because of failure to understand exactly how the VPHP works, in fact VHPS is quite simple.

MARCO PAGANI

**MARKETING & COMMUNICATION MANAGER
IWT SRL**

THE NEW EMERALD ER1800 FOR RATS

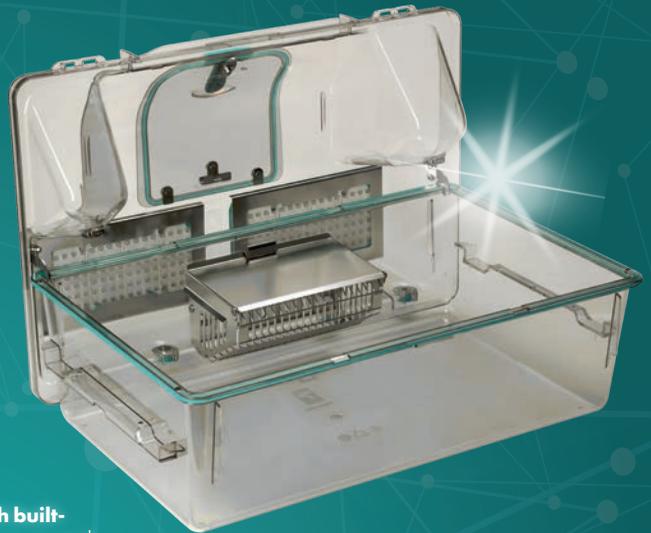
EMERAT IVC

The EMERAT ER1800 is the new IVC for rats, the new arrival in Emerald Family. Thanks to some successful innovations, it is able to guarantee four main advantages that make this cage unique:

OPERATOR COMFORT

The EMERAT's **SmarTop** represents the best ergonomic solution for operators which satisfies the highest requirements for standardisation and biosecurity. The SmarTop assists in the aseptic practices: with a simple motion of lifting the lid, it is possible to perform standardised procedures during the cage change with any potential cross-contamination minimised.

Moreover, thanks to its lightness and the presence of **moulded cage runners with built-in handles**, EMERAT ER1800 allows greater ergonomics when transferring the cage on and off the rack.



ANIMAL WELFARE

The new design makes EMERAT ER1800 not only a simple cage but **a real rat suite**. The absence of a stainless steel lid and the dual use of the feeder, which also works as a mezzanine thanks to the solid lid, provide to animals an enriched and fully accessible internal environment. In this way, they are free to express natural behaviour patterns whilst promoting positive behavioural traits, such as exploration and bi-pedal posture.

VISIBILITY

The **latch-free innovative design** guarantees unrivalled visibility, providing a clear, unrestricted view allowing daily health and welfare checks to be carried out easily. The Tecniplast **PATENTED** cage sealing design combined with **the in-bedded locking system** guarantees the optimal protection for both animals and operators.



VERSATILITY

EMERAT ER1800 is a versatile system with two great IVC rack styles to meet every facilities requirements. The **ERGO Racks** allow operators to easily access all cages in any position comfortably. But, if the space is a premium, the **HD Racks** are the ideal solution to increase the cage density and save space in the vivarium.



WATCH PRODUCT VIDEO

EMERAT ER1800 represents the ideal solution to offer operator comfort and animal welfare in a single cage, now hand in hand.

ERGO RACK: 5 ROWS

HD RACK: 6 ROWS



THE TECNIPLAST HOUSING TEAM

PANORAMA MEETS... SANTA CLAUS!

There is a great value in charitable actions: the gratitude of those in need.

Efisio Spanu, "Tecniplast's Santa Claus", tells us about the good soul of Tecniplast.



Efisio, you are the valued and estimated Service Corporate Director at Tecniplast/IWT. However, we saw you in an atypical custom at Christmas!

Try to visualize Tecniplast as an active giant with a good soul: the day-to-day activities keep us busy and motivated, but this does not prevent us from realizing how lucky we are in our comfortable context and investing efforts, energies and time to provide tangible help to those who are in desperate need of essential things in life.

We focus our attentions on less fortunate families with children, and to reach them directly we network with local schools, caseworkers and soup-kitchens.

The initiative we pictured was the **"Christmas basket for families in need"**: friends and colleagues sponsored food, hygiene items and toys that were directly delivered to those in need... an immense gift for people in need and a great humanitarian experience for us.

How was the Corporate participation?

The response from the Company, the colleagues and friends was overwhelming: we could not only deliver food and joy to 60 local disadvantaged families, but we also saved a huge amount of food that was welcomed at the soup-kitchen. **Meeting the people who benefitted from our efforts was a touching experience:** decaying rooms

lacking everything and filled with smells that will never leave our memory were clashing with unaware children playing joyfully with what toys they had...

Can you summarize all the TP initiatives taken in 2021 to support unlucky people?

13 years ago we founded the "Support Bank", with which we take care of the primary needs of less fortunate families. **We cover primary needs offering food, medicines and paying bills.**

We also developed more complex projects like job requalification for parents or micro-credit with no interests. We are also supporting with money and manpower two local soup-kitchens that deliver over 300 meals per day. Finally, we take care of nearly 40 children in a village in Tanzania, accompanying them through the difficulties in a place where nothing is taken for granted, until they are 18 and have a school qualification that helps make them independent.

Our motto is: *"If anybody is hungry do not only offer a fish, teach him/her how to fish."*

Can you tell your feelings and the value of those actions?

Tecniplast is locally perceived as a hub of altruism, yet ready to help - without expecting anything in return - families with kids that are going through a hard time.

Having the opportunity to reach and support directly where the need is present, is good, and motivates us to do more and better.

We are doing nothing special, just sowing the seeds of a better future...

SILVIA DALLA COSTA

**COMMUNICATION & EVENTS MANAGER
TECNIPLAST S.P.A.**

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innovation through passion

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