



AdaCore CASE STUDY

**How Eldorado and Braile Biomédica
Used AdaCore's QGen Code
Generator to Develop New Artificial
Lung Equipment in Just Six Months**

How Eldorado and Braile Biomédica used AdaCore's QGen Code Generator to develop new artificial lung equipment in just six months, increasing the treatment options and survival rates among COVID-19 patients

When COVID-19 hit Brazil, two Brazilian tech institutions came together to help in the fight. Medical device manufacturer Braile Biomédica decided to redesign a device that was in development to create a new device to assist COVID-19 victims experiencing blood oxygen deficits. In partnership with the Eldorado Institute, and utilizing AdaCore's QGen code generation and model verification tool suite, Braile was able to complete a two-year development program in only six months.

Collaborating in the biomedical device arena

The Eldorado Institute (Eldorado) is a private research and technology organization (RTO) in Brazil. Eldorado collaborates with technology companies in Brazil and other countries to develop new products. They join forces with their partners' internal engineering teams on an open-innovation basis.

Eldorado works constantly to expand its realm of expertise into new sectors. A relatively new unit at Eldorado is their medical device division, formed in the last half of 2018.

One of that division's first clients, Braile Biomédica, partnered with Eldorado to develop hyperthermic intraperitoneal chemotherapy (HIPEC) equipment. HIPEC is an oncological treatment that involves abdominal cavity perfusion with heated chemotherapy drugs. Also known as "hot chemotherapy," HIPEC is performed after tumors or lesions are removed from the abdominal area.

Then along come COVID...

When the COVID-19 pandemic exploded in Brazil in March 2020, Braile realized the HIPEC machine that was in development could be redesigned to help patients battling the virus. They decided to change the project that was underway and accelerate the development of this new device, known as the **Solis System**, to help in the fight. The Solis System consists of an extracorporeal membrane oxygenation (ECMO) device, which is designed to support patients with severe lung

Customers

The Eldorado Institute (Eldorado) is a private research and technology organization (RTO) in Brazil that collaborates with technology companies in Brazil and other countries to develop new products. Braile Biomédica is a Brazilian medical devices manufacturer specializing in cardiovascular, endovascular and oncology surgery solutions.

Problem

When COVID-19 hit Brazil, these two Brazilian tech institutions came together to help in the fight. Braile Biomédica decided to redesign a device that was in development to create a new device to assist COVID-19 victims experiencing blood oxygen deficits.

Solution

Eldorado had already begun using AdaCore's QGen code generation and model verification tool suite on a cardiac pacemaker as a pilot project. Once they felt they had a mature understanding of how to design their software architecture for IEC62304, and how to use QGen in code generation and verification, they began applying QGen on other projects. One of those projects was Braile's new Solis System.

Results

With the partnership of Braile, the Eldorado Institute, and AdaCore's QGen, it was possible to complete a two-year development program in only six months.

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— Fernando Arruda, Product Development Specialist, Braile Biomédica

“It’s imperative the system be reliable,” says Fernando Arruda, the Project Development Specialist at Braile responsible for development of the ECMO. “The easiest way to assure high reliability is by using model-based systems engineering (MBSE) techniques to design and test the system, and then to generate the code for the target controller hardware directly from the model using an automated code generator.”

Simulation and automated code generation also speed time to market, by allowing developers to develop a working model, test it, and generate code for the target hardware far faster than they can craft handwritten code.

Fortunately, when COVID-19 struck, Eldorado already had a solution in hand.

The search for a safety-critical code generation tool

In 2017, Eldorado began looking for model verification and code generation tools. They were already using MBSE for some time, but they wanted to get away from tools used primarily for university research. They felt they should migrate toward platforms designed for development of commercial products, especially those built for safety-critical systems.

Eldorado also understood that automated code generation could reduce development time and risk, which could give them and their partners a competitive edge in the market.

“If the tool we chose did not generate highly reliable code, we would end up rewriting a lot of it manually,” says Guilherme Fonseca, Manager of Research & Development at Eldorado. “We would lose time and money throughout the development process. We would have higher risk, because we would not be sure the code behaves exactly like the model. We would also risk not gaining regulatory approval for our devices. Software validation, verification, and reliability have become extremely

injuries, keeping the patient alive until the lung recovers and the disease regresses. The machine, combined with a set of disposable devices, performs the circulation and oxygenation of the patient’s blood outside the body.

The COVID emergency and the pressure generated by the pandemic made this development one of the biggest challenges for Braile and Eldorado.

First, time was of the essence. The rapidly mounting number of COVID-19 cases in Brazil and worldwide was creating enormous demand for medical devices to assist patients with breathing and blood oxygenation. Braile and Eldorado had to work quickly.

Second, the device had to be extremely reliable, regardless of the tight development timeframe. Treatments could last as long as thirty-forty days, during which time the ECMO is responsible for keeping the patient alive. High reliability in such a device is critical to patient survival.

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important for regulatory agencies the last few years, because software code size and complexity in medical devices has been growing rapidly.”

They had other concerns, as well. Would the license fees fit their project budgets and be feasible for their clients? Would the tool fit their current MBSE strategy? How long would it take their engineers to become proficient with the tool? Would the code and documentation be of high quality?

Not long after they began their search, Eldorado’s R&D team came across QGen.

Finding not only a tool, but a collaborative partner

QGen, by AdaCore, is a qualifiable and tunable code generation and model verification tool suite designed for a safe subset of Simulink® and Stateflow® models.

“During our evaluation, QGen demonstrated it can deliver excellent code for these types of applications, and AdaCore showed us very good partnership and support”

— **Guilherme Fonseca, Manager, Research & Development, ELDORADO**

Eldorado contacted AdaCore and began a trial evaluation of QGen. They tried it out on some models they had already built. They did the same thing with two competing products and compared results. Eldorado found that QGen best matched their requirements and provided the best overall value. This is largely due to the easily readable generated code, and the warranty of equivalence of behavior between the generated code and simulation.

They were also impressed by AdaCore’s willingness to collaborate. “During our evaluation, QGen demonstrated it can deliver excellent code for these types of applications, and AdaCore showed us very good partnership and support,” Fonseca said.

Applying QGen on medical device development

Following their evaluation, Eldorado immediately began exploring ways to use QGen in biomedical applications.

Eldorado has been upgrading its development processes to comply with IEC 62304, the international standard for medical device software and software lifecycle processes. They are using QGen to generate code for IEC 62304 Class C software—software used in applications where death or serious injury to the patient is possible. The standard requires deep software design documentation and deep testing for Class C software.

Fonseca says Eldorado takes a “correct by construction” approach to developing their Class C software. They construct a mathematical model of their design before any code is produced. The model is then used to reason about the proposed solution, ensuring that all required functionality will be delivered, and the correct behavior exhibited. Testing is performed, but its role is to validate the correct-by-construction process rather than to find bugs.

“You can ensure that all the parameters and the features are tested in advance in a simulated environment,” says Fonseca. “Then after generating the code and loading it into the actual machine, you can compare the simulation with the real environment and see if there are any discrepancies. With the model simulation for comparison, it’s easier to determine what caused the mismatch and to correct it, which helps make the system safer and more reliable.”

Eldorado began using QGen on a cardiac pacemaker as a pilot project. Once they felt they had a mature understanding of how to design their software architecture for IEC62304, and how to use QGen in code generation and verification, they began applying QGen on other projects. One of those projects was Braile’s ECMO.

Two years' development in six months

Braile's Arruda points out that one of the biggest benefits of using an automated code generator like QGen is the enormous savings in time to market.

"We are not relying on the software generation process for the product's reliability. For that, we rely on system testing," he says. "At the same time, if we cannot rely on the software development process and tools, we would have to do more testing, because we would be finding and correcting more bugs."

"Doing all that additional testing and bug fixing would lengthen the schedule. So, naturally if we cannot rely on the coding tools, we are not going to use them. We are not relying on code generation for the safety of the product, but more for efficiency of development."

Or as Arruda put it to his board of directors: thanks to Eldorado's model-based process and QGen, they were able to condense a two-year product development process down to six months.

"When we did the very first trial of the system it was practically done," he said. "The software just needed a few "look and feel" adjustments to the user interface, but all the requirements were tested and verified quickly when we did the first hardware/software integration. The adjustments were only to address user perception comments, not usability issues."

"Because the model was stable, we were able to simply adjust some parameters within the model, and the issues were corrected in minutes. All we had to do then was regenerate the code. The users were impressed by how easily and quickly we were able to make changes to the system."

Confidence to take on high-risk projects

Fonseca concurs. "Applying QGen in our development process helped a lot. We could change the system very quickly while maintaining high reliability in what would otherwise be a high-risk product," he said.

"Using QGen is essentially a risk mitigation strategy. Through simulation and code generation we can ensure the system will provide the correct functionality. AdaCore's ongoing qualification of the QGen

toolset for use in safety-critical aerospace applications gives us confidence that the QGen code generator will be of the highest quality. We believe it will always produce code that matches the results we have validated through simulation."

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According to Fonseca, this risk mitigation strategy has given Eldorado confidence to take on projects that would otherwise be quite risky. "It has opened for us the possibility of entering other markets we had not been aiming for prior to our partnership with AdaCore," he said.

Adding value to client relationship

Fonseca also feels QGen elevates them in the eyes of their clients, and elevates their clients in the eyes of the clients' customers.

"When a client like Braile shows their customers how fast we can make, test and deliver any required changes, that's good for the client, and it's also good for us," he says. "It demonstrates that Eldorado adds value to the client's customer relationship. So, they'll want to continue doing business with us on future projects."

Another way QGen adds value, says Fonseca, is by delivering clean, readable code.

“Our clients don’t need to buy a QGen license to work with us,” says Fonseca. “Once they have the source code in hand, they can easily understand how each part is developed. They can continue to develop it themselves if they wish. We believe that’s another advantage for Eldorado.”

“I have no record or recollection of any issue that took too long to be addressed or resolved.”

— Guilherme Fonseca, Manager, Research & Development, ELDORADO

One last benefit of QGen that Fonseca cited is the support Eldorado has received from AdaCore. “Our team was very satisfied with the overall attention and support the AdaCore technical team gave us,” he said. “I have no record or recollection of any issue that took too long to be addressed or resolved.”

Outlook and Plans for the Future

Eldorado’s immediate plans for QGen include an upgrade to Braile’s ECMO. At the time of this writing, Braile was working on defining new features for the device. The upgrade project is scheduled to begin in 2021. Eldorado’s immediate plans for QGen include an upgrade to Braile’s ECMO. At the time of this writing, Braile was working on defining new features for the device. The upgrade project is scheduled to begin in 2021.

Braile and Eldorado have also developed a roadmap of other projects that includes redesign. Due to their safety-critical nature, Fonseca expects to use QGen in developing the application layer for those products, as well.

In the meantime, Fonseca and his team plan to leverage QGen to attract other partners in the medical device sector and in other industries.

“If there’s any opportunity that demands development of high-risk, high-reliability software, we are going to use QGen to verify our model and generate high-reliability code,” says Fonseca.

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About AdaCore

Founded in 1994, AdaCore supplies software development and verification tools for mission-critical, safety-critical, and security-critical systems. The company has its North American headquarters in New York and its European headquarters in Paris.

AdaCore products are open source and come with expert online support provided by the developers themselves. Among those products is QGen, their model-based development tool suite for safety-critical control systems. QGen provides a qualifiable and customizable code generator and static verifier for a safe subset of Simulink and Stateflow models, along with a model-level debugger. For more information on QGen, visit adacore.com/qgen.

About Eldorado

The Eldorado Institute (Eldorado) is a private Research and Technology Organization (RTO) in Brazil that works with companies to develop new products in several industry sectors. Eldorado works as an external research development team with an open-innovation perspective. They join forces with their partners' internal engineering teams and, together, they and their partners generate new products on an open-innovation basis. The medical device division at Eldorado is relatively new, having been formed in the first half of 2018. The markets they address include ventilators, ICU equipment, ECG and EEG diagnostics, physiotherapy, dermatology, cardiac surgery, and oncological surgery, among others.

About Braile Biomédica

Braile Biomédica is a Brazilian medical devices manufacturer specializing in cardiovascular, endovascular and oncology surgery solutions. Its product portfolio includes disposable perfusion devices, biological cardiac prostheses, stent-graft stents, electromedical equipment, transcatheter valves, and an intraperitoneal perfusion system. They are market leaders for biological heart valves in Russia and in many countries of the Middle East as well as Latin America. Braile is currently investing to expand its oncology surgery business in partnership with Eldorado.